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(54) PULSE DETECTION USING PATIENT PHYSIOLOGICAL SIGNALS

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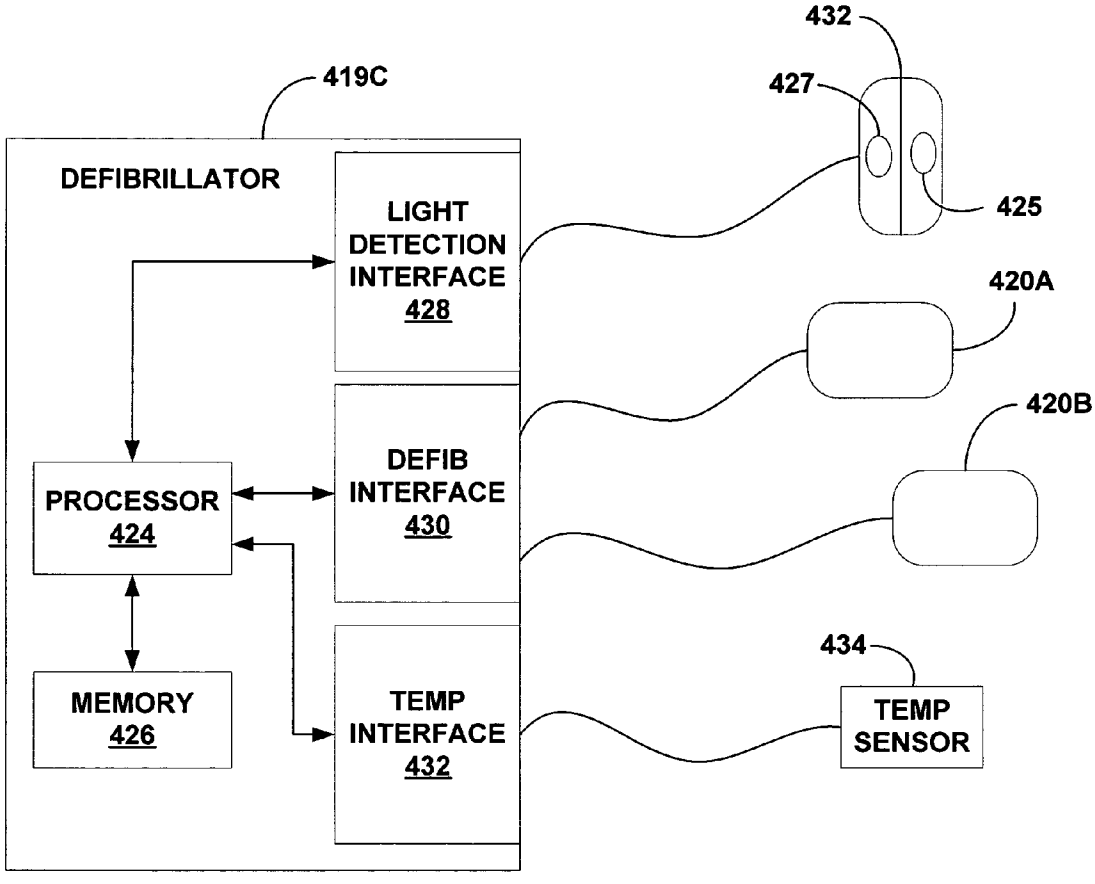
Publication Classification

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(52) **U.S. Cl.** **607/6**; 600/500

(57) **ABSTRACT**

The presence of a cardiac pulse in a patient is determined by evaluating physiological signals in the patient. In one embodiment, a medical device evaluates optical characteristics of light transmitted into a patient to ascertain physiological signals, such as pulsatile changes in general blood volume proximate a light detector module. Using these features, the medical device determines whether a cardiac pulse is present in the patient. The medical device may also be configured to report whether the patient is in a VF, VT, asystole, or PEA condition, in addition to being in a pulseless condition, and prompt different therapies, such as chest compressions, rescue breathing, defibrillation, and PEA-specific electrotherapy, depending on the analysis of the physiological signals. Auto-capture of a cardiac pulse using pacing stimuli is further provided.



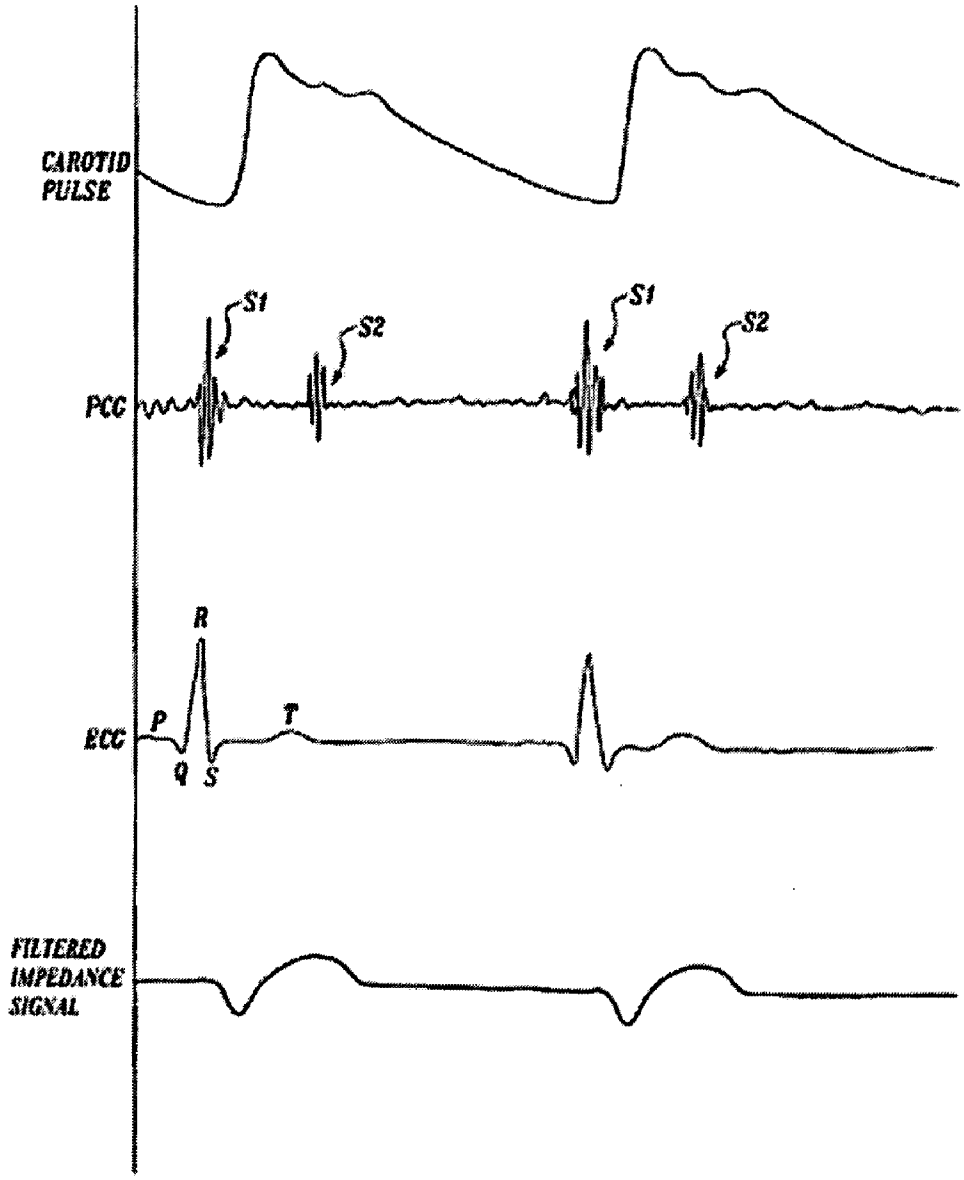

CAROTID PULSE
S1
S2
S1
S2
PCG
R
P
T
Q
S
ECG
FILTERED IMPEDANCE SIGNAL

Fig. 1.

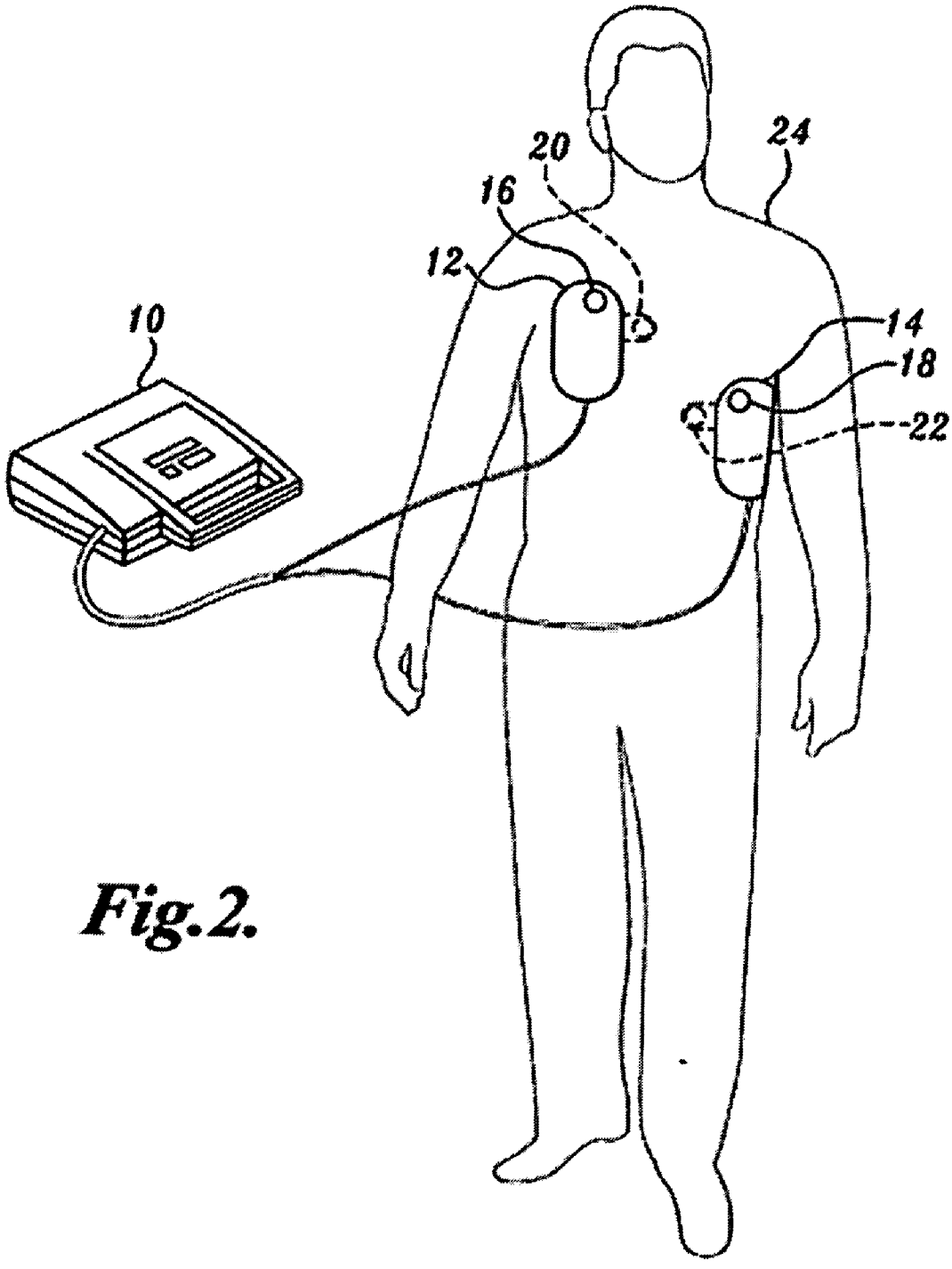


Fig.2.

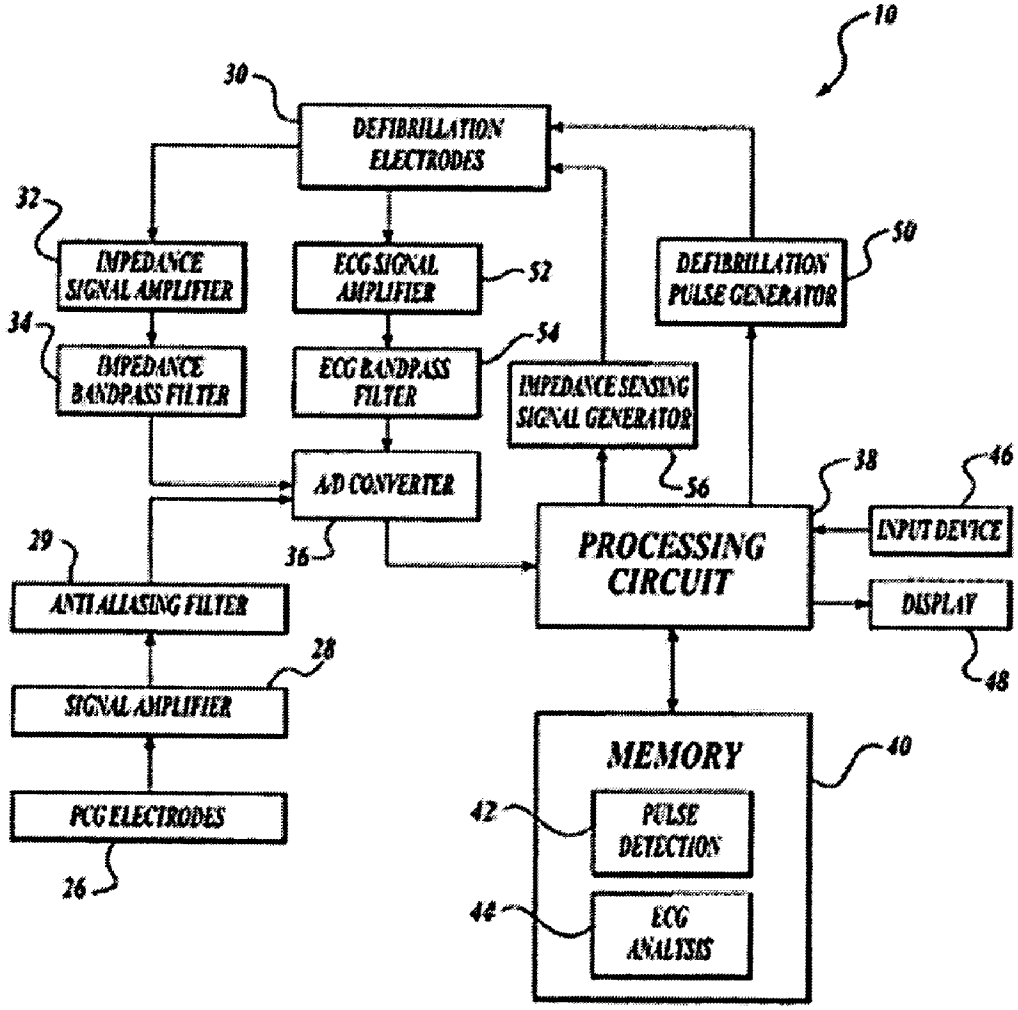

10
30
DEFIBRILLATION ELECTRODES
32
IMPEDANCE SIGNAL AMPLIFIER
ECG SIGNAL AMPLIFIER
52
DEFIBRILLATION PULSE GENERATOR
50
34
IMPEDANCE BANDPASS FILTER
ECG BANDPASS FILTER
54
IMPEDANCE SENSING SIGNAL GENERATOR
A/D CONVERTER
56
38
46
PROCESSING CIRCUIT
INPUT DEVICE
29
36
ANTI ALIASING FILTER
DISPLAY
48
28
SIGNAL AMPLIFIER
MEMORY
40
42
PULSE DETECTION
PCG ELECTRODES
44
ECG ANALYSIS
26

Fig. 3.

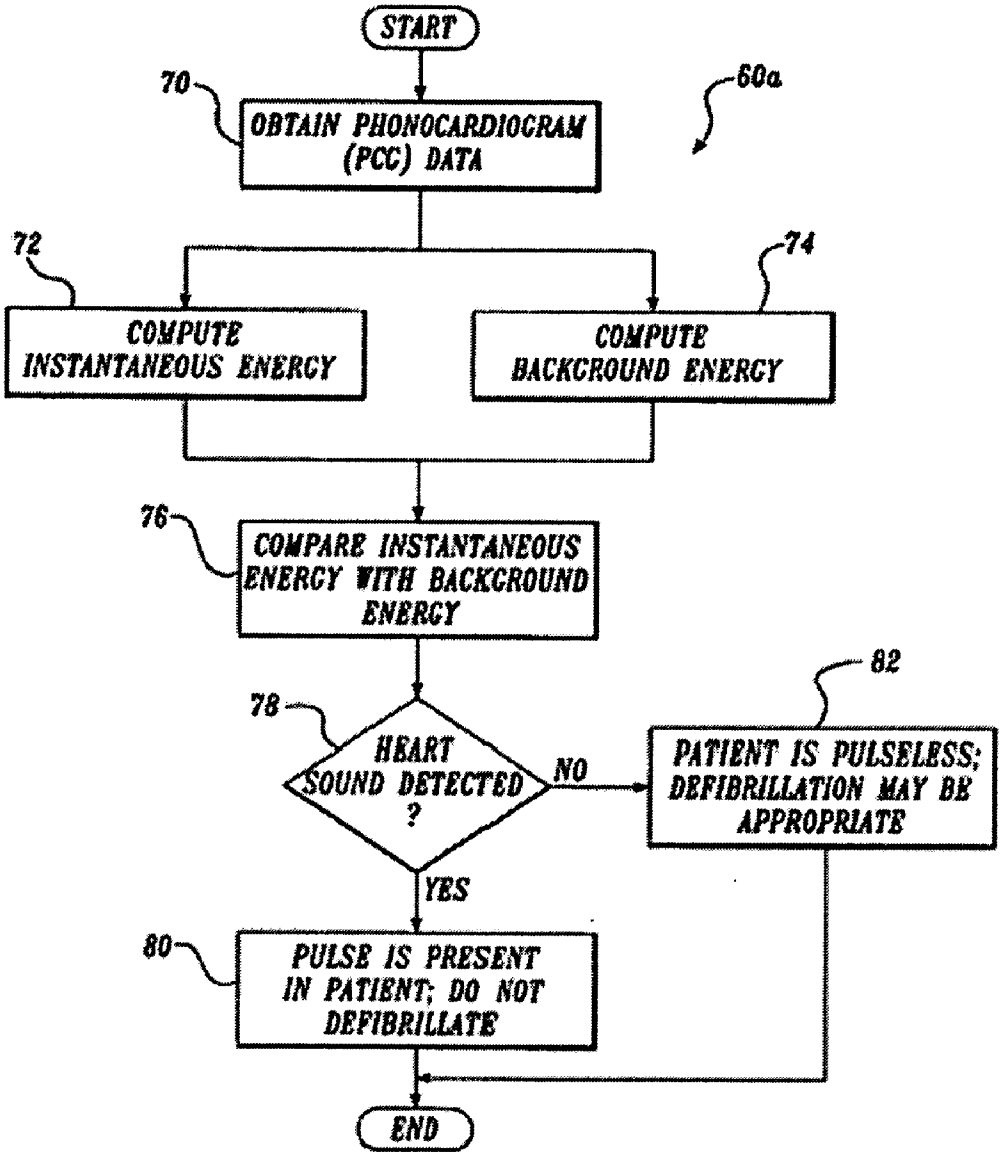

START
70
OBTAIN PHONOCARDIOGRAM (PCG) DATA
60a
72
COMPUTE INSTANTANEOUS ENERGY
74
COMPUTE BACKGROUND ENERGY
76
COMPARE INSTANTANEOUS ENERGY WITH BACKGROUND ENERGY
78
HEART SOUND DETECTED ?
NO
82
PATIENT IS PULSELESS; DEFIBRILLATION MAY BE APPROPRIATE
YES
80
PULSE IS PRESENT IN PATIENT; DO NOT DEFIBRILLATE
END

FIG. 4

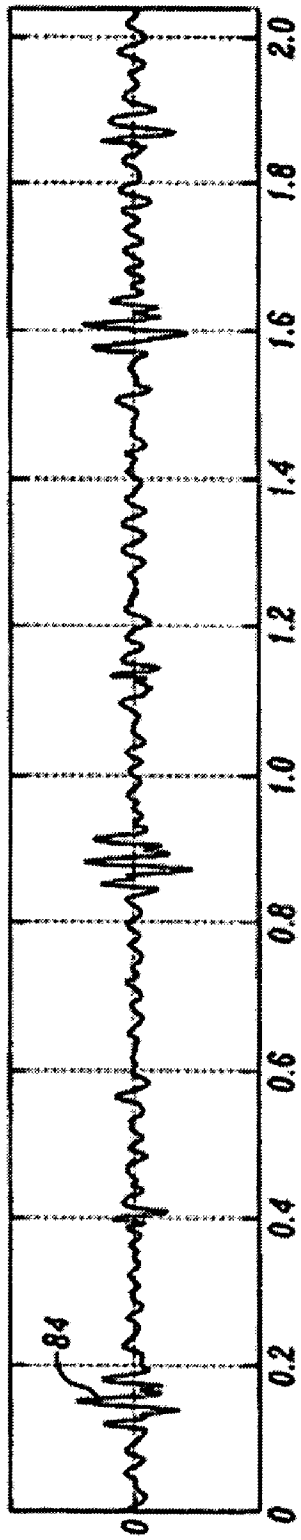


Fig. 5A.

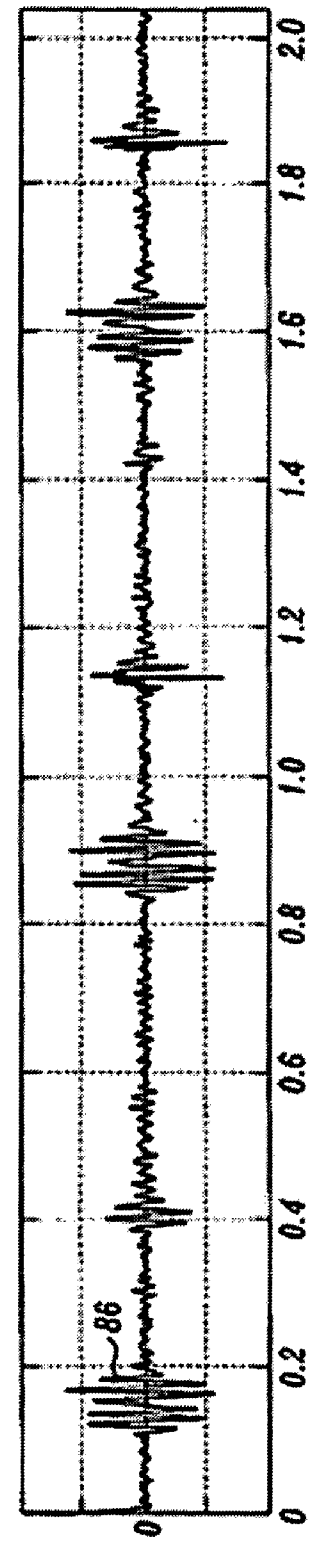


Fig. 5B.

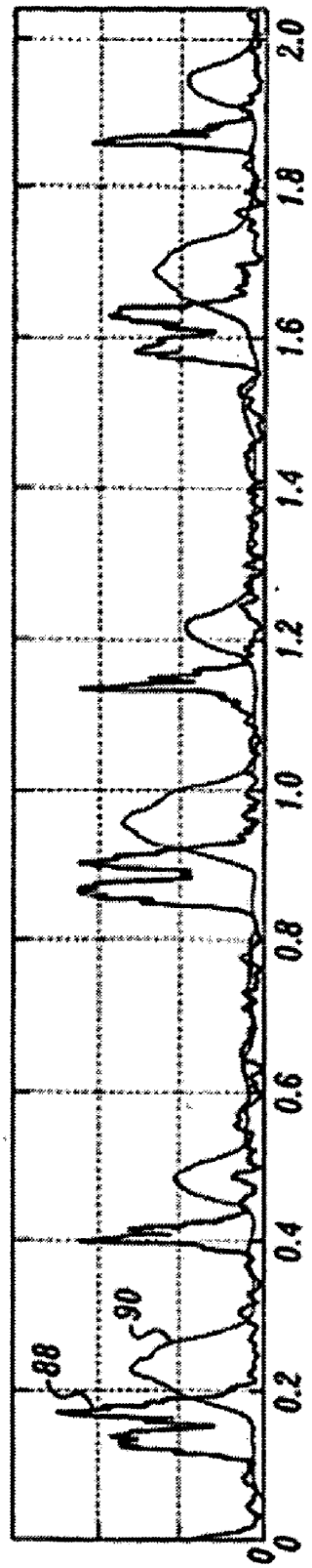

0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0
88
90

Fig.5C.

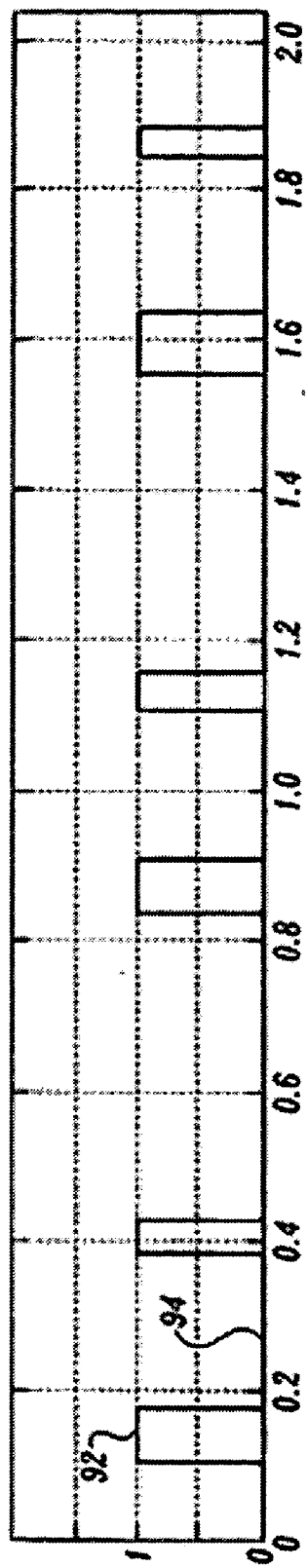

0
1
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0
92
94

Fig.5D.

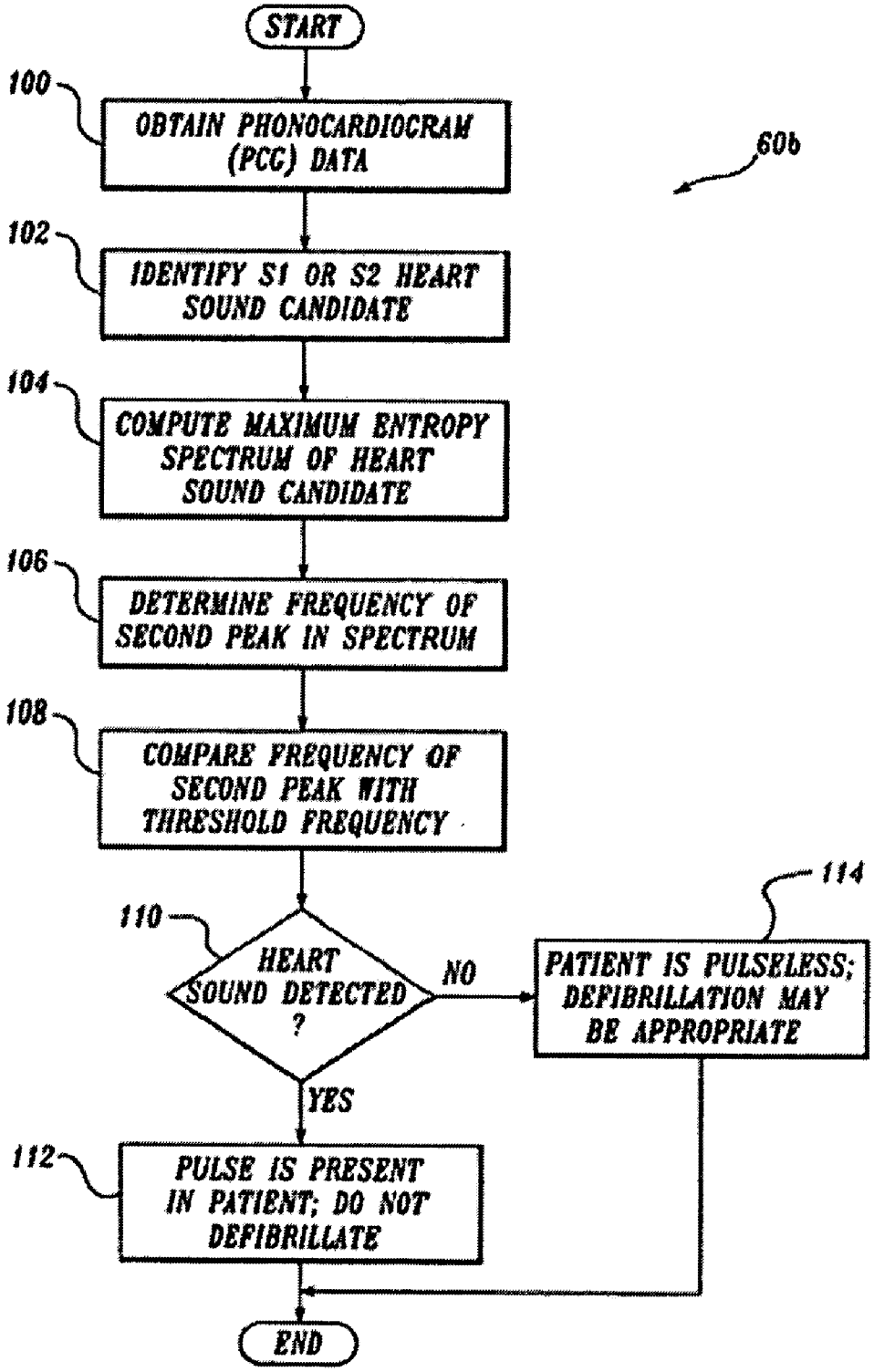

START
100
OBTAIN PHONOCARDIOGRAM (PCG) DATA
60b
102
IDENTIFY S1 OR S2 HEART SOUND CANDIDATE
104
COMPUTE MAXIMUM ENTROPY SPECTRUM OF HEART SOUND CANDIDATE
106
DETERMINE FREQUENCY OF SECOND PEAK IN SPECTRUM
108
COMPARE FREQUENCY OF SECOND PEAK WITH THRESHOLD FREQUENCY
110
HEART SOUND DETECTED ?
NO
114
PATIENT IS PULSELESS; DEFIBRILLATION MAY BE APPROPRIATE
YES
112
PULSE IS PRESENT IN PATIENT; DO NOT DEFIBRILLATE
END

Fig. 6.

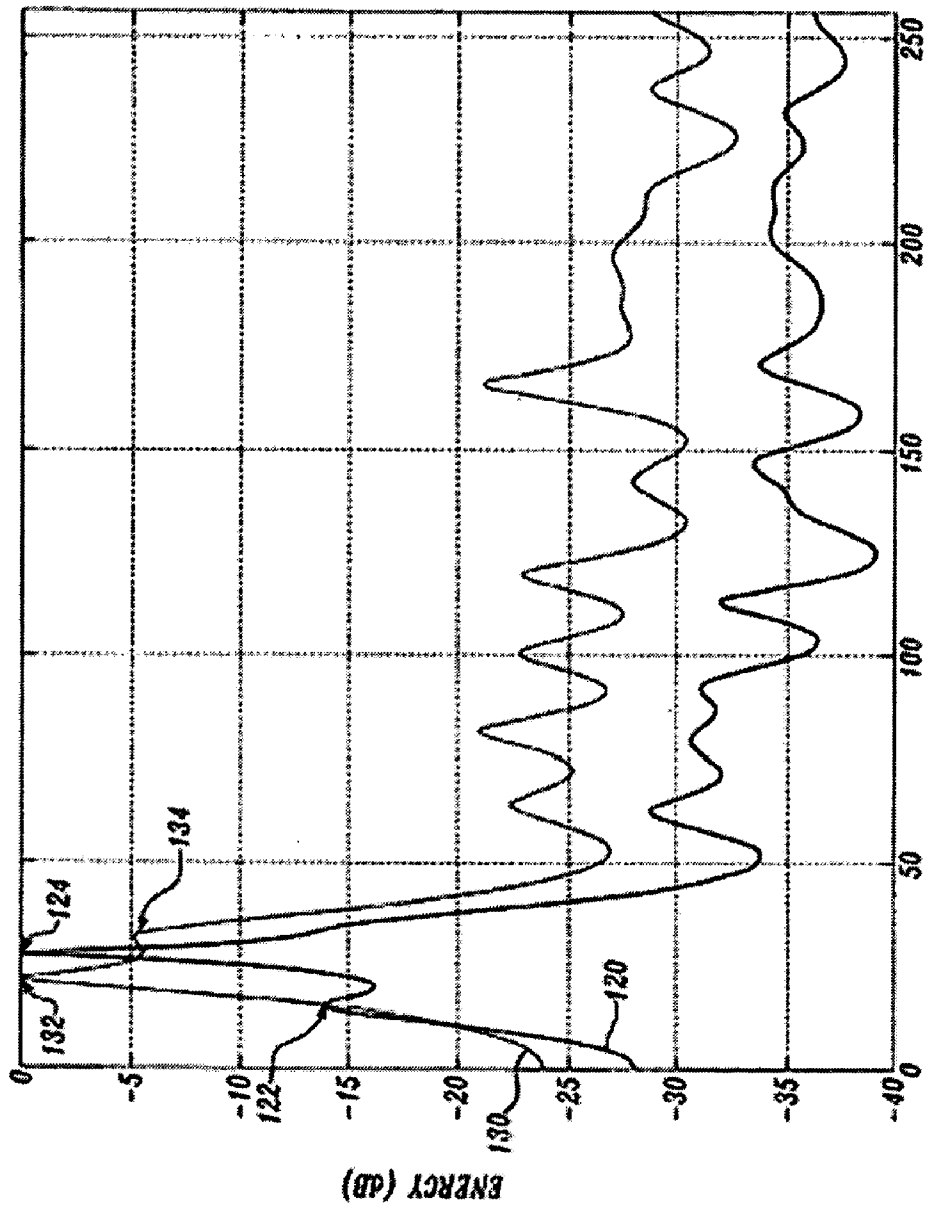

ENERGY (dB)
FREQUENCY (Hz)
0
-5
-10
-15
-20
-25
-30
-35
-40
0
50
100
150
200
250
120
122
124
130
132
134

Fig. 7.

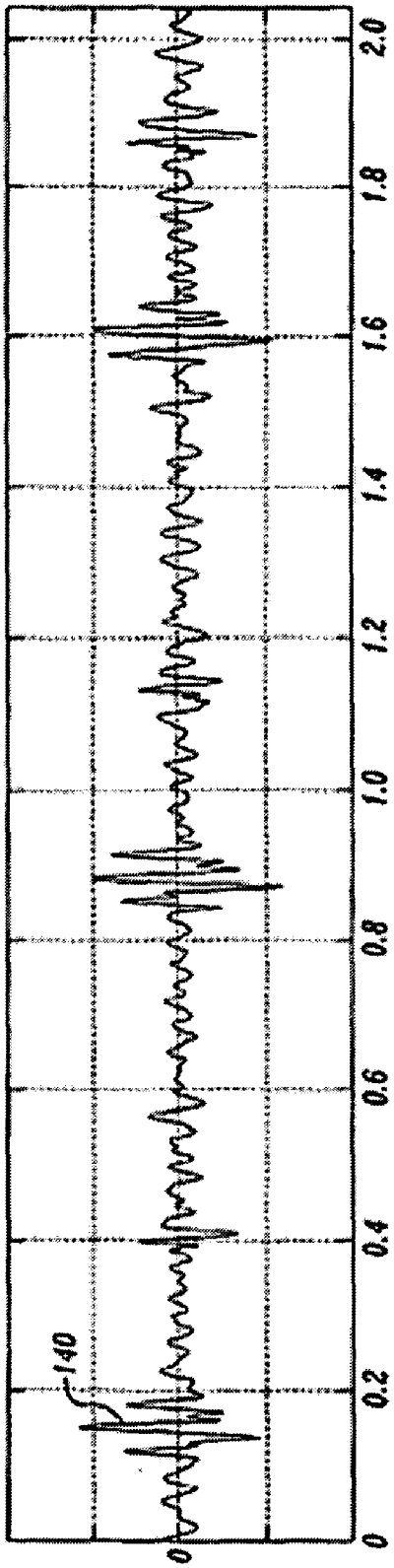


Fig.8A.

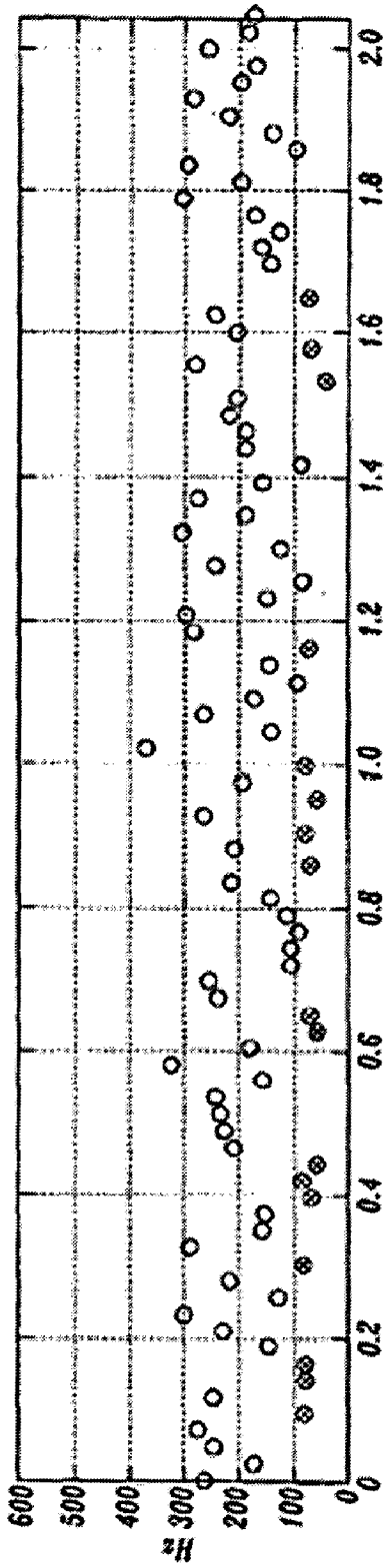

Hz
600
500
400
300
200
100
0
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0

Fig.8B.

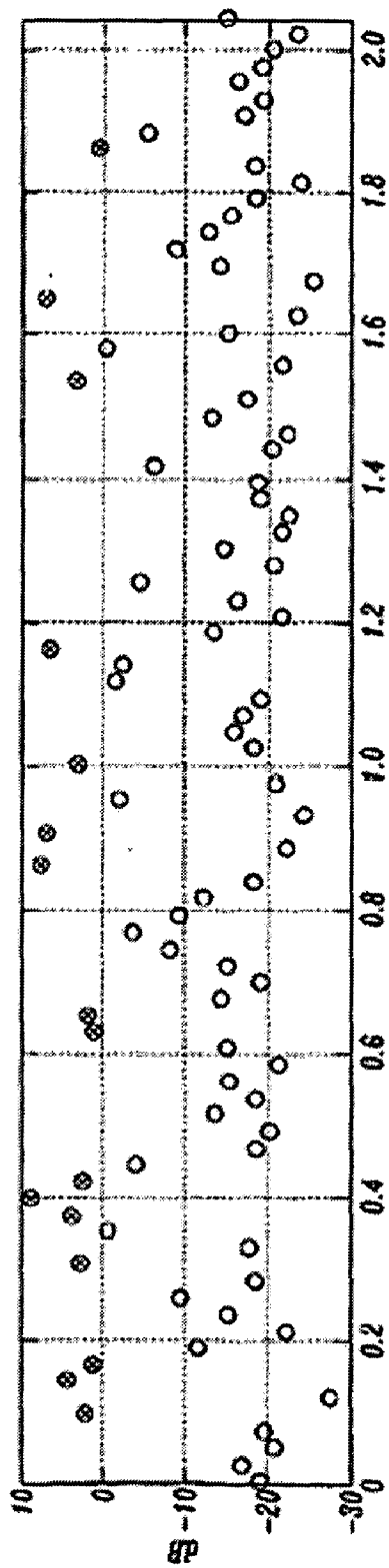

dB
10
0
-10
-20
-30
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0

Fig.8C.

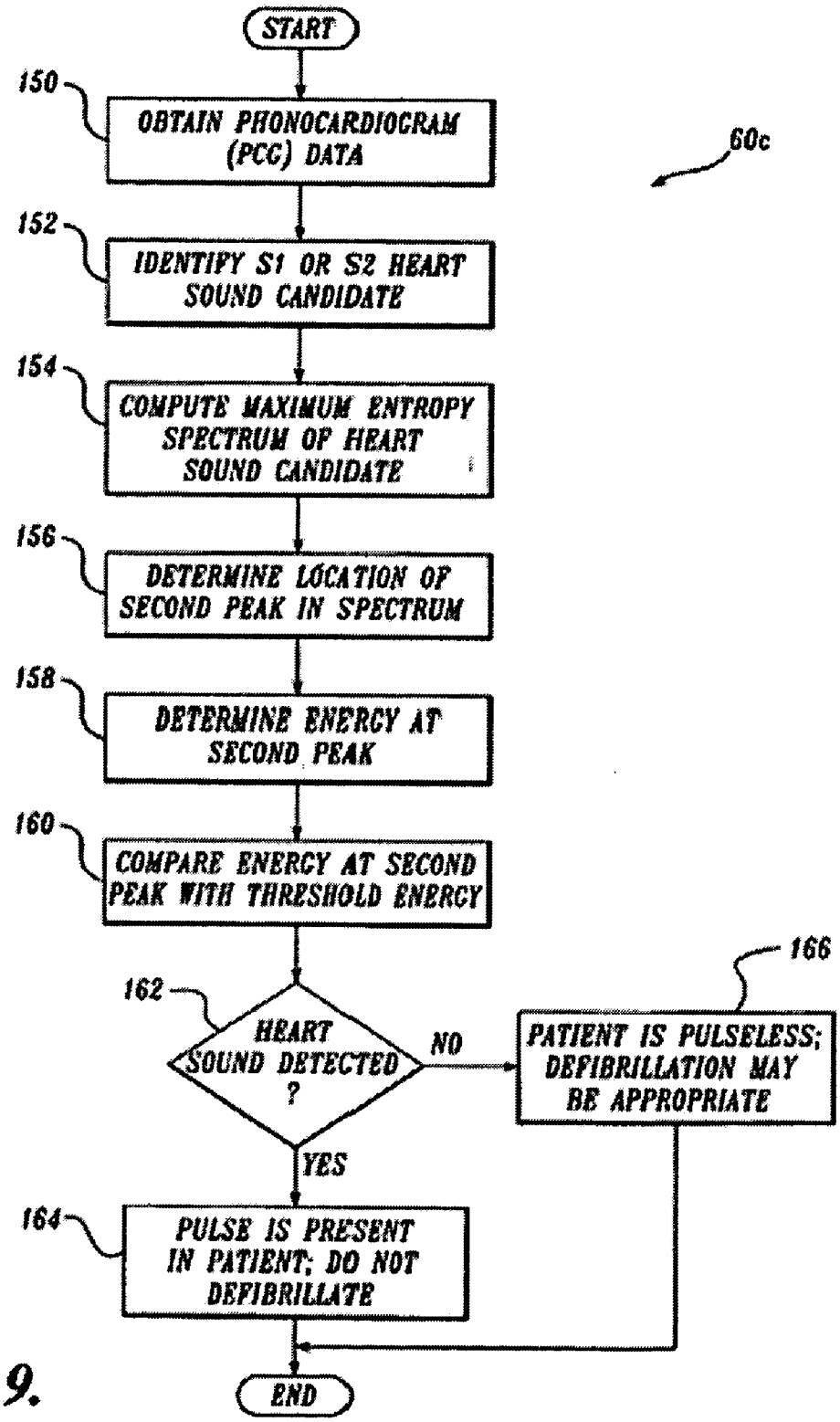

START
150
OBTAIN PHONOCARDIOGRAM (PCG) DATA
60c
152
IDENTIFY S1 OR S2 HEART SOUND CANDIDATE
154
COMPUTE MAXIMUM ENTROPY SPECTRUM OF HEART SOUND CANDIDATE
156
DETERMINE LOCATION OF SECOND PEAK IN SPECTRUM
158
DETERMINE ENERGY AT SECOND PEAK
160
COMPARE ENERGY AT SECOND PEAK WITH THRESHOLD ENERGY
162
HEART SOUND DETECTED ?
NO
166
PATIENT IS PULSELESS; DEFIBRILLATION MAY BE APPROPRIATE
YES
164
PULSE IS PRESENT IN PATIENT; DO NOT DEFIBRILLATE
END

Fig. 9.

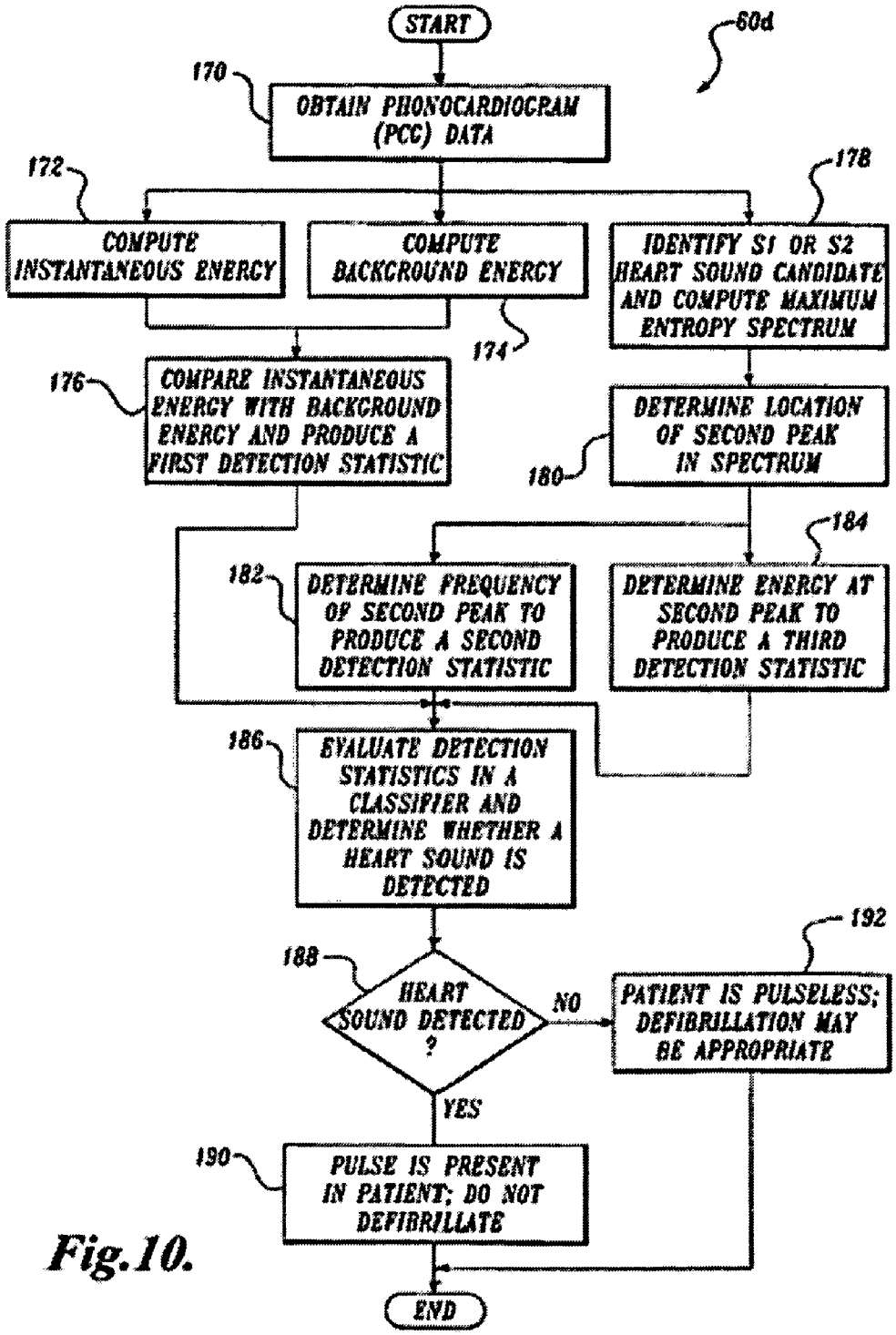

START
60d
170
OBTAIN PHONOCARDIOGRAM (PCG) DATA
172
178
COMPUTE INSTANTANEOUS ENERGY
COMPUTE BACKGROUND ENERGY
IDENTIFY S1 OR S2 HEART SOUND CANDIDATE AND COMPUTE MAXIMUM ENTROPY SPECTRUM
174
176
COMPARE INSTANTANEOUS ENERGY WITH BACKGROUND ENERGY AND PRODUCE A FIRST DETECTION STATISTIC
DETERMINE LOCATION OF SECOND PEAK IN SPECTRUM
180
184
182
DETERMINE FREQUENCY OF SECOND PEAK TO PRODUCE A SECOND DETECTION STATISTIC
DETERMINE ENERGY AT SECOND PEAK TO PRODUCE A THIRD DETECTION STATISTIC
186
EVALUATE DETECTION STATISTICS IN A CLASSIFIER AND DETERMINE WHETHER A HEART SOUND IS DETECTED
192
188
HEART SOUND DETECTED ?
NO
PATIENT IS PULSELESS; DEFIBRILLATION MAY BE APPROPRIATE
YES
190
PULSE IS PRESENT IN PATIENT; DO NOT DEFIBRILLATE
END

Fig.10.

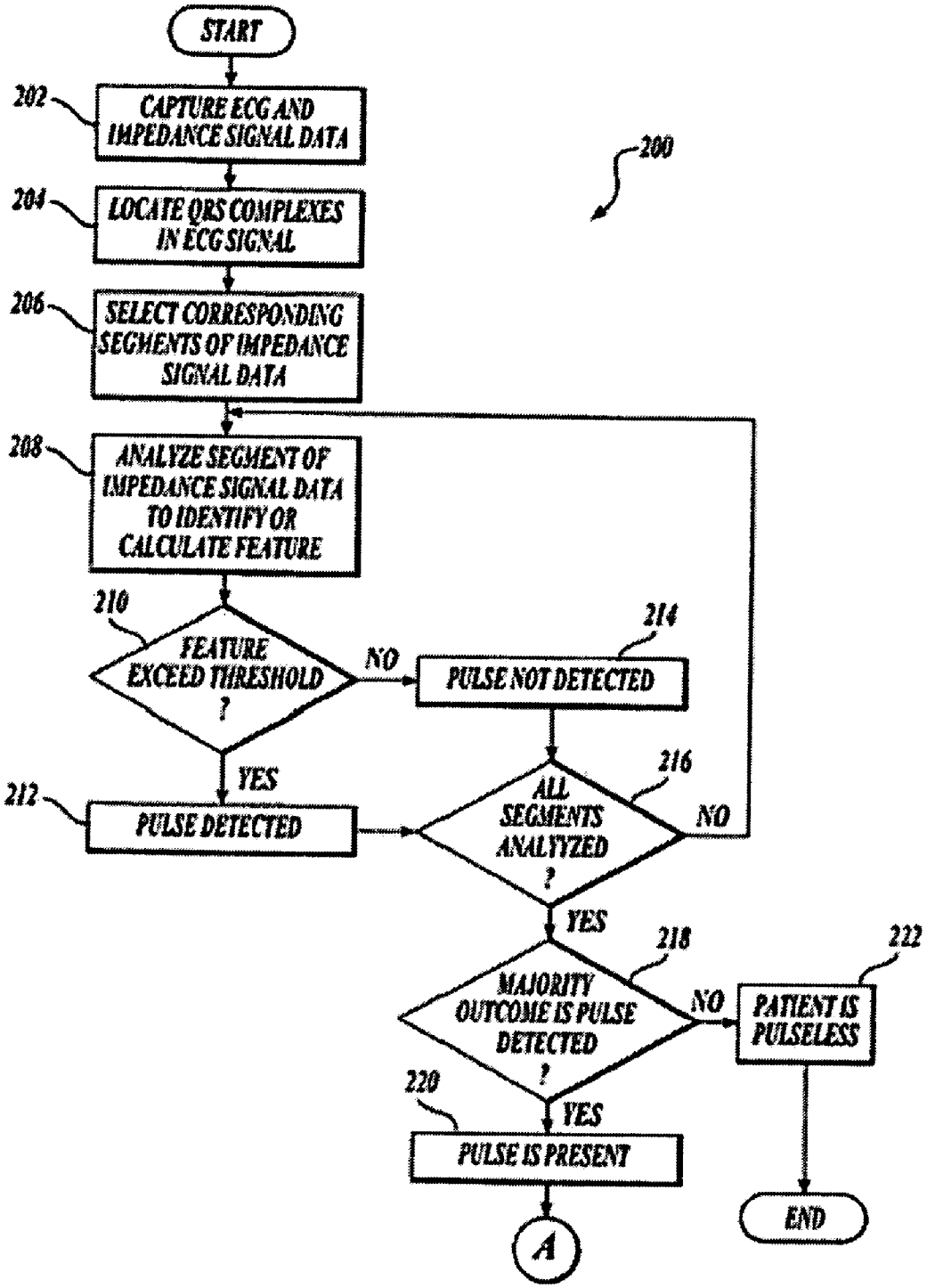

START
202
CAPTURE ECG AND IMPEDANCE SIGNAL DATA
200
204
LOCATE QRS COMPLEXES IN ECG SIGNAL
206
SELECT CORRESPONDING SEGMENTS OF IMPEDANCE SIGNAL DATA
208
ANALYZE SEGMENT OF IMPEDANCE SIGNAL DATA TO IDENTIFY OR CALCULATE FEATURE
210
FEATURE EXCEED THRESHOLD ?
NO
214
PULSE NOT DETECTED
YES
212
PULSE DETECTED
216
ALL SEGMENTS ANALYZED ?
NO
YES
218
MAJORITY OUTCOME IS PULSE DETECTED ?
NO
222
PATIENT IS PULSELESS
220
YES
PULSE IS PRESENT
END
A

Fig.11.

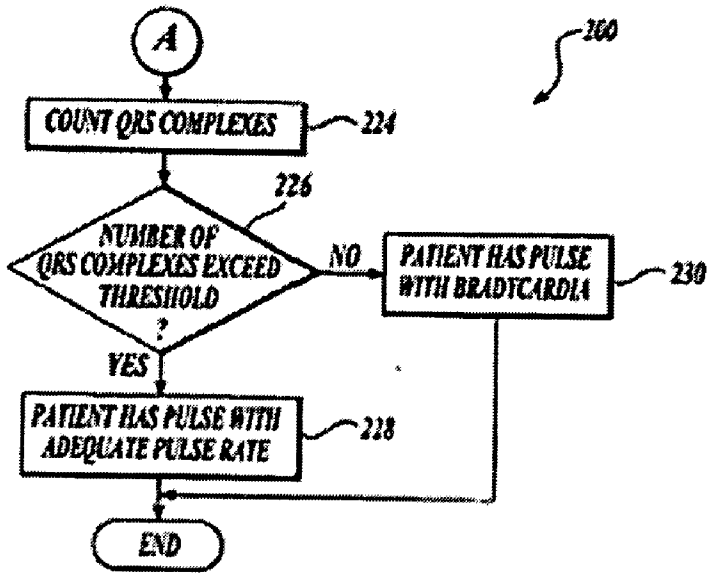

A
COUNT QRS COMPLEXES
224
226
NUMBER OF QRS COMPLEXES EXCEED THRESHOLD ?
NO
PATIENT HAS PULSE WITH BRADYCARDIA
230
YES
PATIENT HAS PULSE WITH ADEQUATE PULSE RATE
228
END

Fig.12.

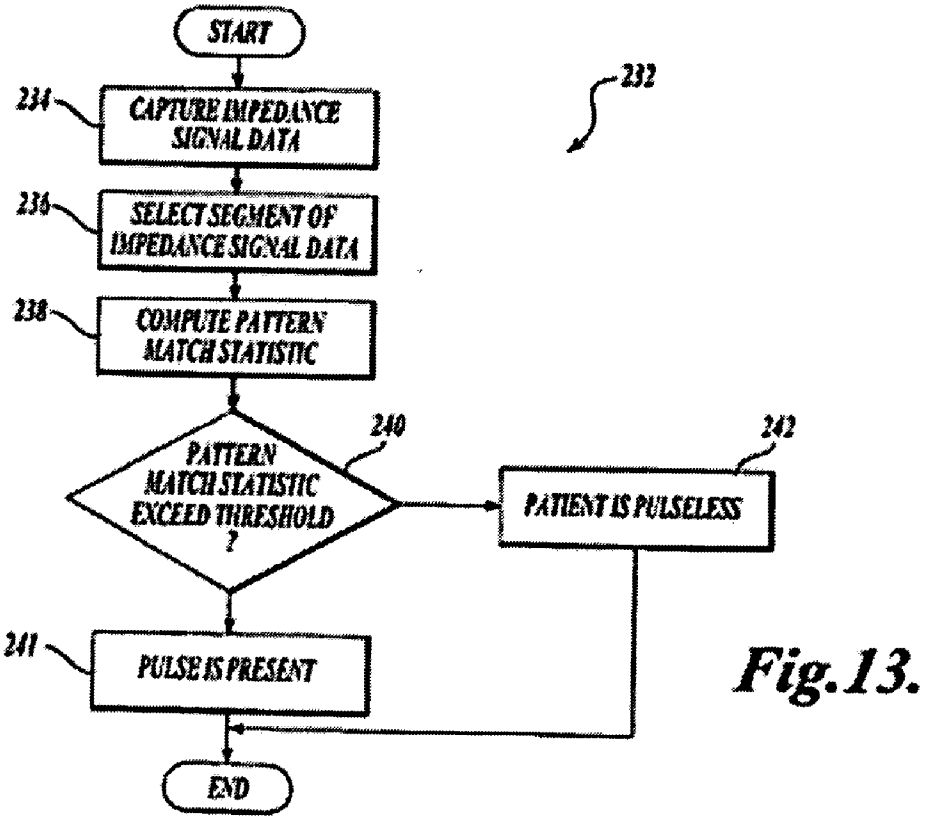

START
234
CAPTURE IMPEDANCE SIGNAL DATA
236
SELECT SEGMENT OF IMPEDANCE SIGNAL DATA
238
COMPUTE PATTERN MATCH STATISTIC
240
PATTERN MATCH STATISTIC EXCEED THRESHOLD ?
242
PATIENT IS PULSELESS
241
PULSE IS PRESENT
END

Fig.13.

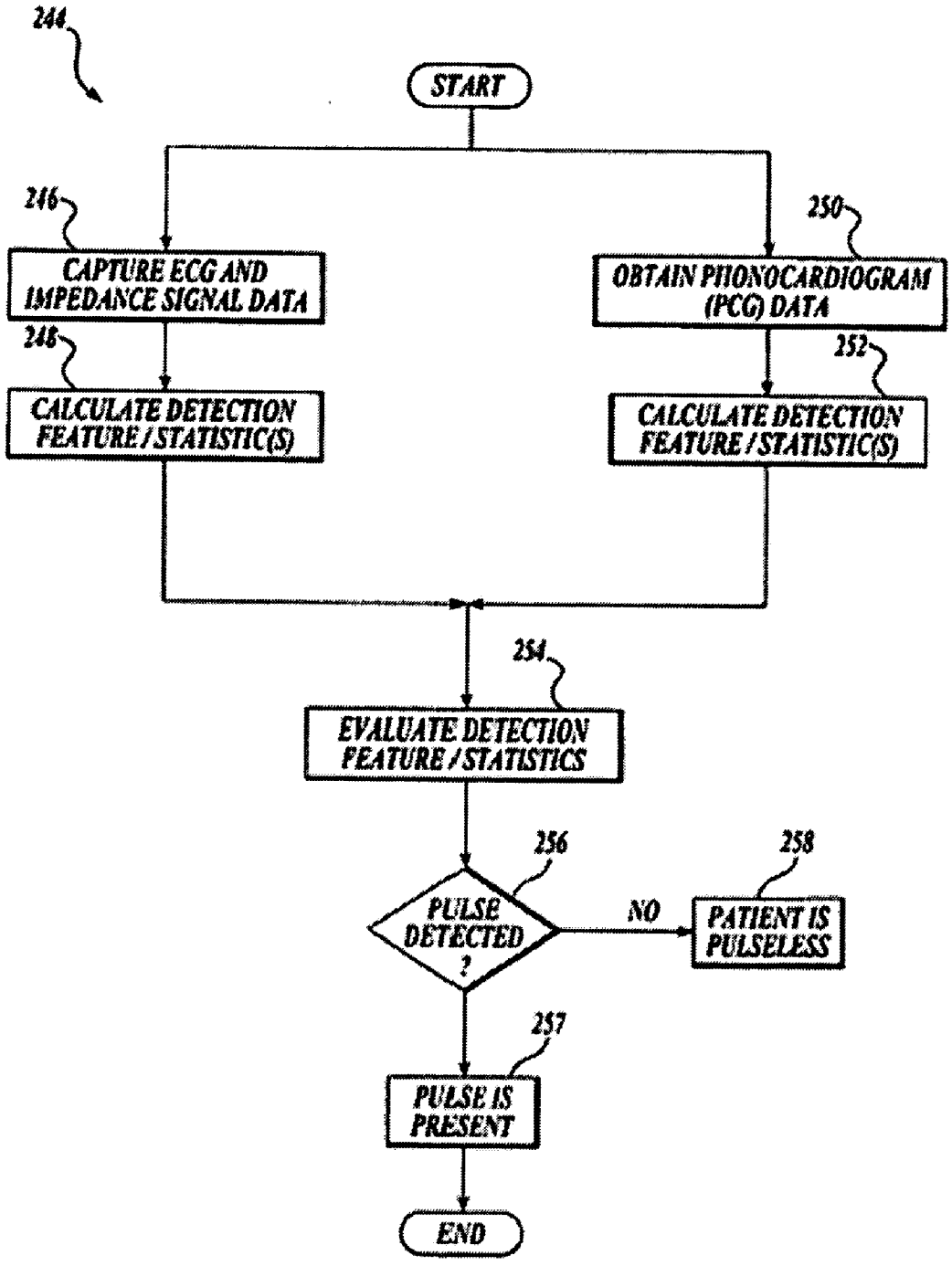

244
START
246
CAPTURE ECG AND IMPEDANCE SIGNAL DATA
248
CALCULATE DETECTION FEATURE / STATISTIC(S)
250
OBTAIN PHONOCARDIOGRAM (PCG) DATA
252
CALCULATE DETECTION FEATURE / STATISTIC(S)
254
EVALUATE DETECTION FEATURE / STATISTICS
256
PULSE DETECTED ?
NO
258
PATIENT IS PULSELESS
257
PULSE IS PRESENT
END

Fig. 14.

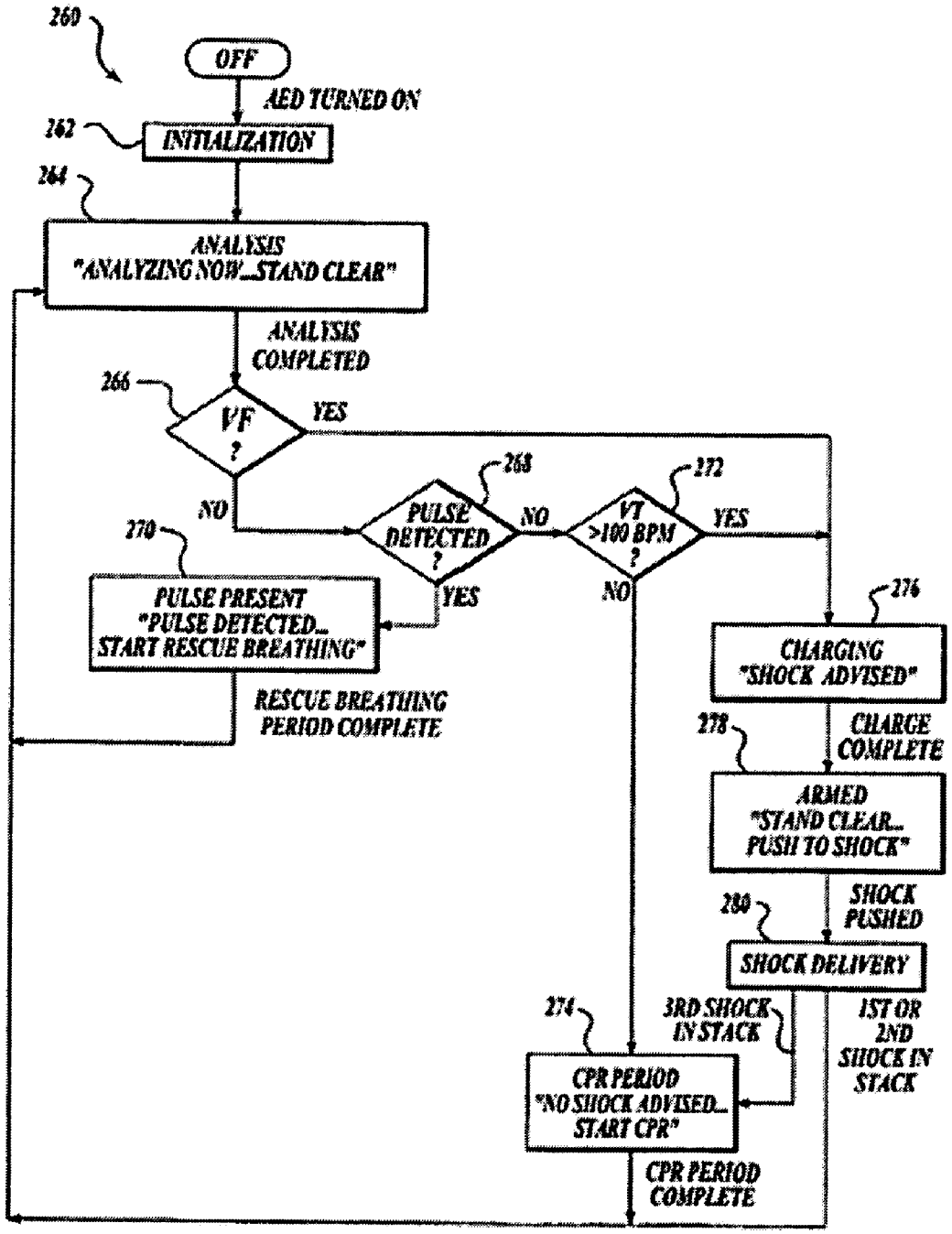

260
OFF
AED TURNED ON
262
INITIALIZATION
264
ANALYSIS
"ANALYZING NOW...STAND CLEAR"
ANALYSIS
COMPLETED
266
VF
?
YES
NO
268
PULSE
DETECTED
?
NO
YES
272
VT
>100 BPM
?
YES
NO
270
PULSE PRESENT
"PULSE DETECTED...
START RESCUE BREATHING"
RESCUE BREATHING
PERIOD COMPLETE
276
CHARGING
"SHOCK ADVISED"
278
CHARGE
COMPLETE
ARMED
"STAND CLEAR...
PUSH TO SHOCK"
280
SHOCK
PUSHED
SHOCK DELIVERY
3RD SHOCK
IN STACK
1ST OR
2ND
SHOCK IN
STACK
274
CPR PERIOD
"NO SHOCK ADVISED...
START CPR"
CPR PERIOD
COMPLETE

Fig.15.

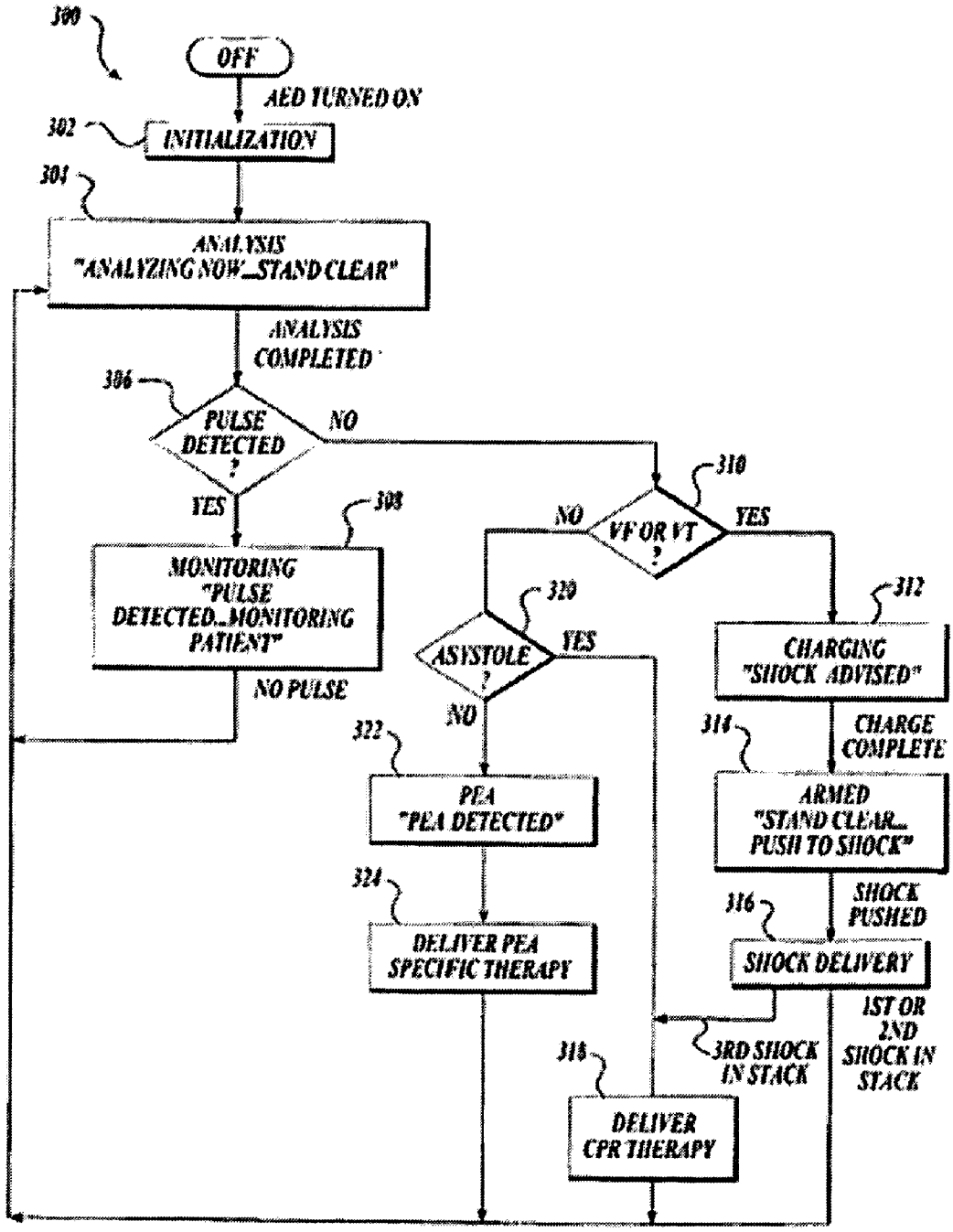

300
OFF
AED TURNED ON
302
INITIALIZATION
304
ANALYSIS
"ANALYZING NOW"_STAND CLEAR"
ANALYSIS
COMPLETED
306
PULSE
DETECTED
?
NO
YES
308
MONITORING
"PULSE
DETECTED_MONITORING
PATIENT"
NO PULSE
310
NO
VF OR VT
?
YES
320
ASYSTOLE
?
YES
NO
312
CHARGING
"SHOCK ADVISED"
314
CHARGE
COMPLETE
ARMED
"STAND CLEAR...
PUSH TO SHOCK"
316
SHOCK
PUSHED
SHOCK DELIVERY
1ST OR
2ND
SHOCK IN
STACK
3RD SHOCK
IN STACK
322
PEA
"PEA DETECTED"
324
DELIVER PEA
SPECIFIC THERAPY
318
DELIVER
CPR THERAPY

Fig.16.

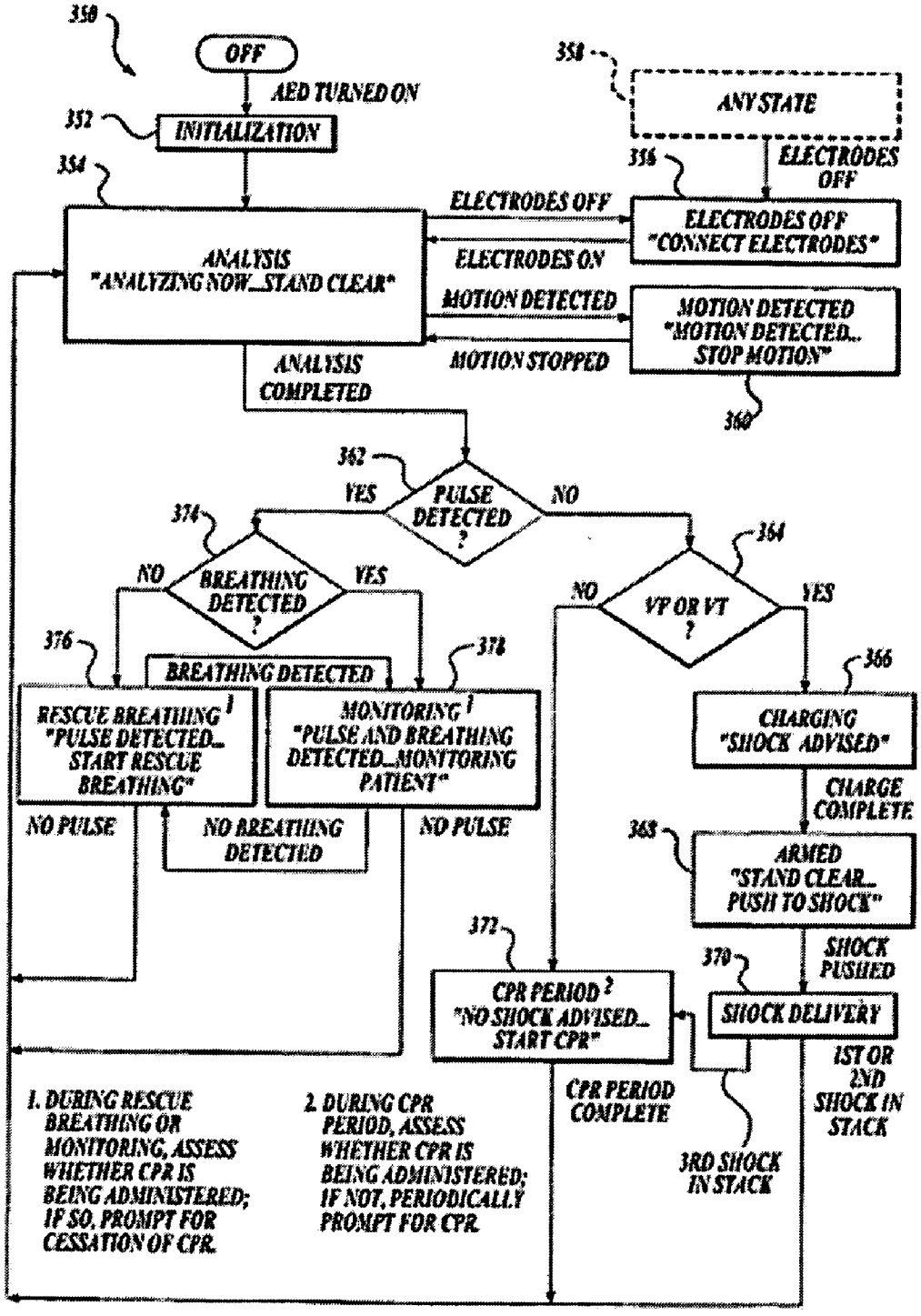

350
OFF
AED TURNED ON
352
INITIALIZATION
354
ANALYSIS
"ANALYZING NOW...STAND CLEAR"
358
ANY STATE
ELECTRODES OFF
356
ELECTRODES OFF
"CONNECT ELECTRODES"
ELECTRODES OFF
ELECTRODES ON
MOTION DETECTED
MOTION STOPPED
MOTION DETECTED
"MOTION DETECTED...
STOP MOTION"
360
ANALYSIS COMPLETED
362
PULSE DETECTED ?
YES
NO
374
BREATHING DETECTED ?
NO
YES
364
VF OR VT ?
NO
YES
376
BREATHING DETECTED
378
RESCUE BREATHING 1
"PULSE DETECTED...
START RESCUE
BREATHING"
MONITORING 1
"PULSE AND BREATHING
DETECTED...MONITORING
PATIENT"
366
CHARGING
"SHOCK ADVISED"
CHARGE COMPLETE
368
ARMED
"STAND CLEAR...
PUSH TO SHOCK"
SHOCK PUSHED
370
SHOCK DELIVERY
372
CPR PERIOD 2
"NO SHOCK ADVISED...
START CPR"
NO PULSE
NO BREATHING DETECTED
NO PULSE
CPR PERIOD COMPLETE
3RD SHOCK IN STACK
1ST OR 2ND SHOCK IN STACK
1. DURING RESCUE BREATHING OR MONITORING, ASSESS WHETHER CPR IS BEING ADMINISTERED; IF SO, PROMPT FOR CESSATION OF CPR.
2. DURING CPR PERIOD, ASSESS WHETHER CPR IS BEING ADMINISTERED; IF NOT, PERIODICALLY PROMPT FOR CPR.

Fig. 17.

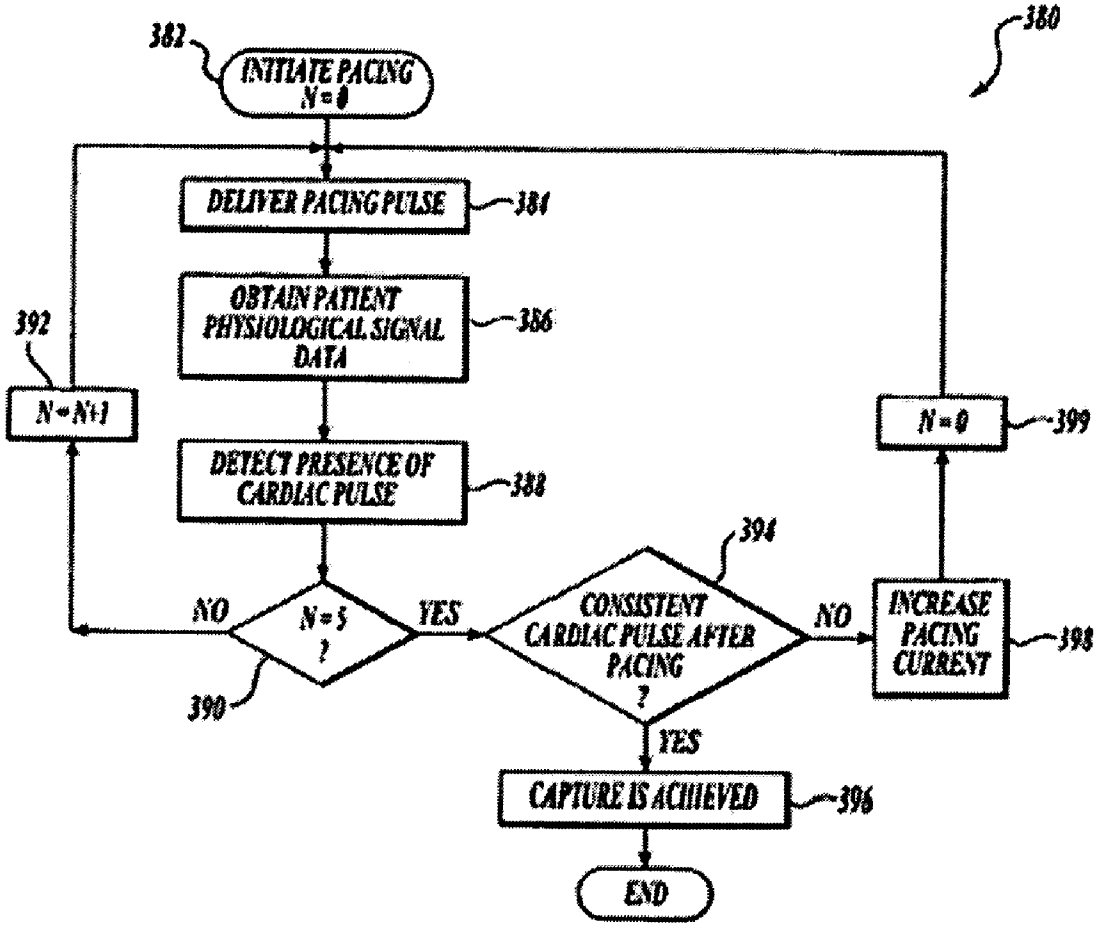

380
382
INITIATE PACING N=0
DELIVER PACING PULSE
384
OBTAIN PATIENT PHYSIOLOGICAL SIGNAL DATA
386
DETECT PRESENCE OF CARDIAC PULSE
388
394
CONSISTENT CARDIAC PULSE AFTER PACING ?
NO
INCREASE PACING CURRENT
398
N=0
399
YES
N=5 ?
NO
YES
390
392
N=N+1
CAPTURE IS ACHIEVED
396
END

Fig. 18.

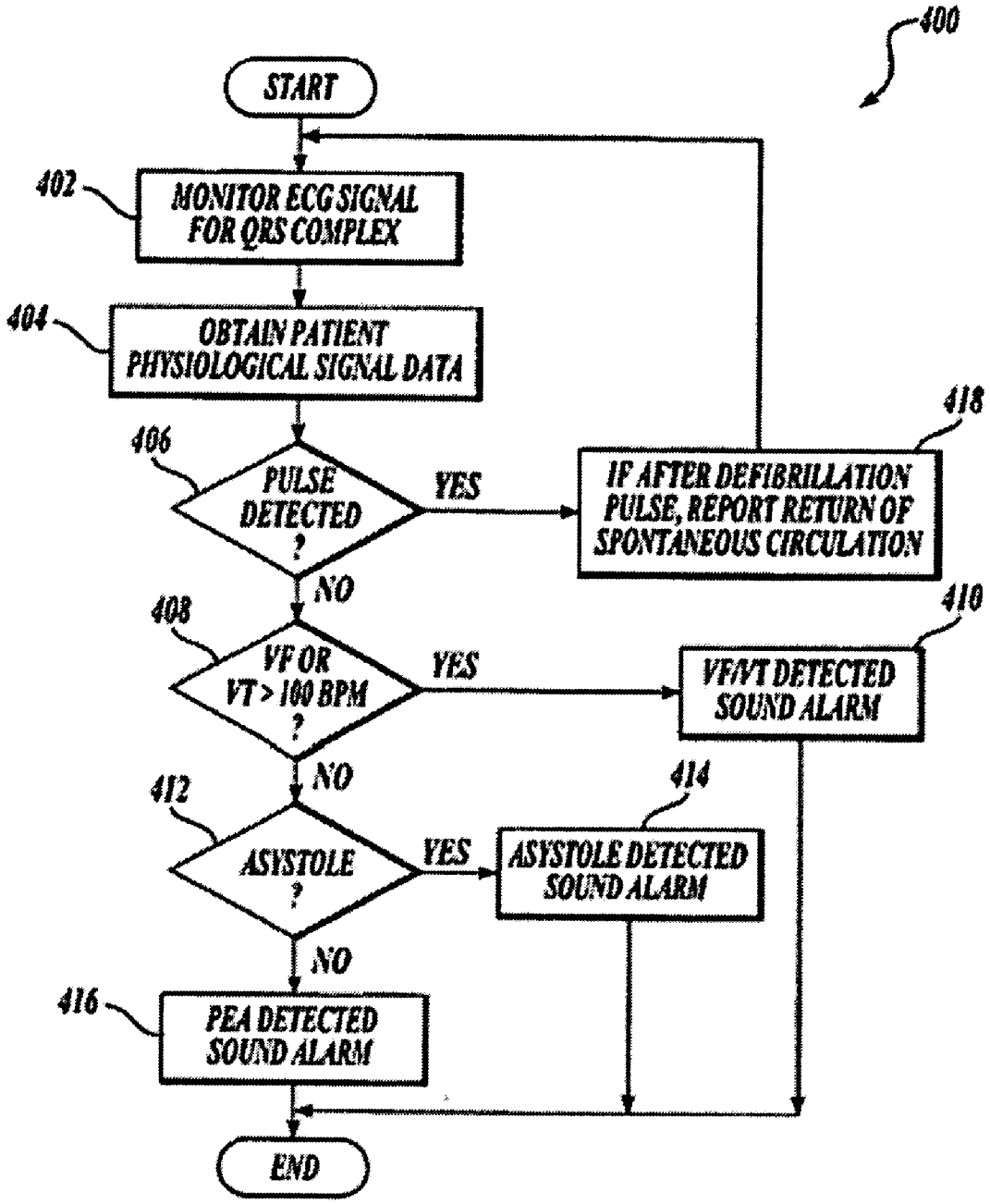

400
START
402
MONITOR ECG SIGNAL FOR QRS COMPLEX
404
OBTAIN PATIENT PHYSIOLOGICAL SIGNAL DATA
406
PULSE DETECTED ?
YES
418
IF AFTER DEFIBRILLATION PULSE, REPORT RETURN OF SPONTANEOUS CIRCULATION
NO
408
VF OR VT > 100 BPM ?
YES
410
VF/VT DETECTED SOUND ALARM
NO
412
ASYSTOLE ?
YES
414
ASYSTOLE DETECTED SOUND ALARM
NO
416
PEA DETECTED SOUND ALARM
END

Fig. 19.

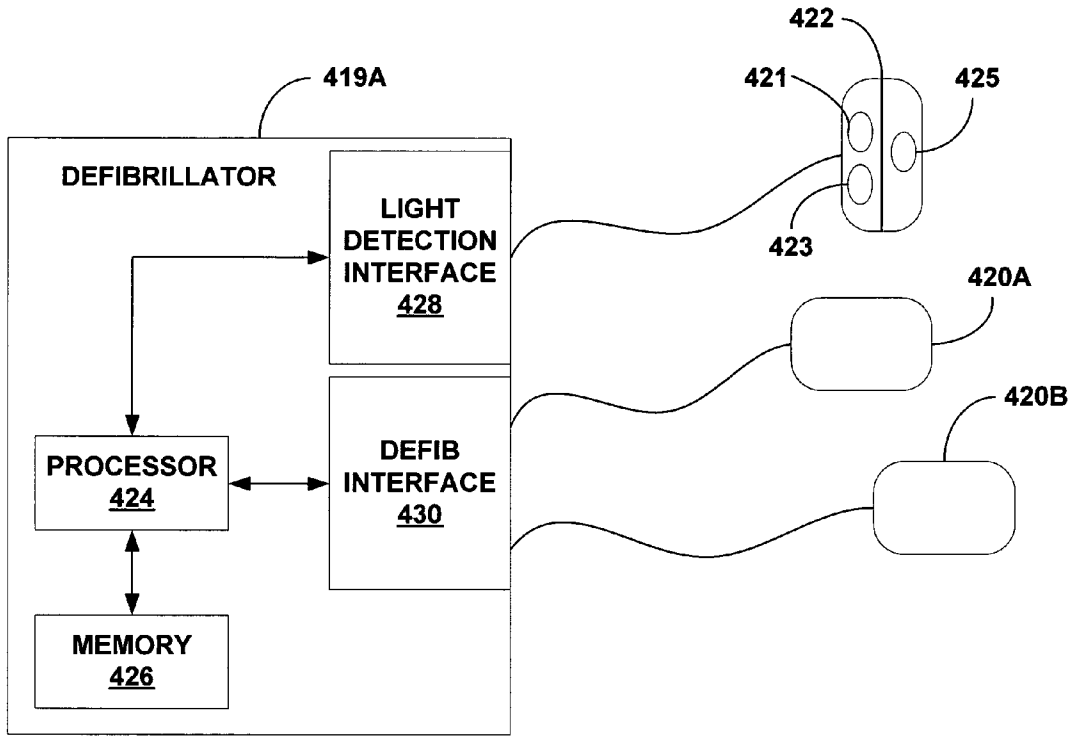

422
421
425
419A
DEFIBRILLATOR
LIGHT DETECTION INTERFACE 428
423
420A
420B
PROCESSOR 424
DEFIB INTERFACE 430
MEMORY 426

FIG. 20

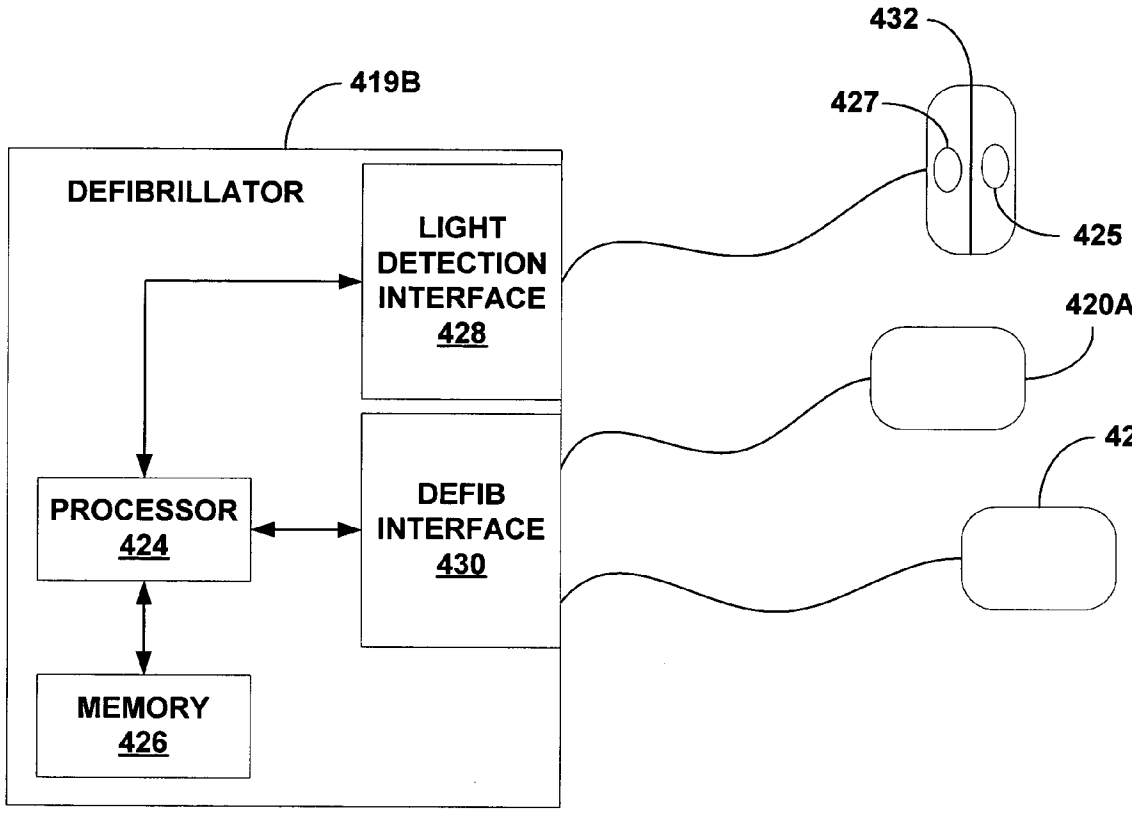

419B
DEFIBRILLATOR
LIGHT DETECTION INTERFACE 428
DEFIB INTERFACE 430
PROCESSOR 424
MEMORY 426
432
427
425
420A

FIG. 21

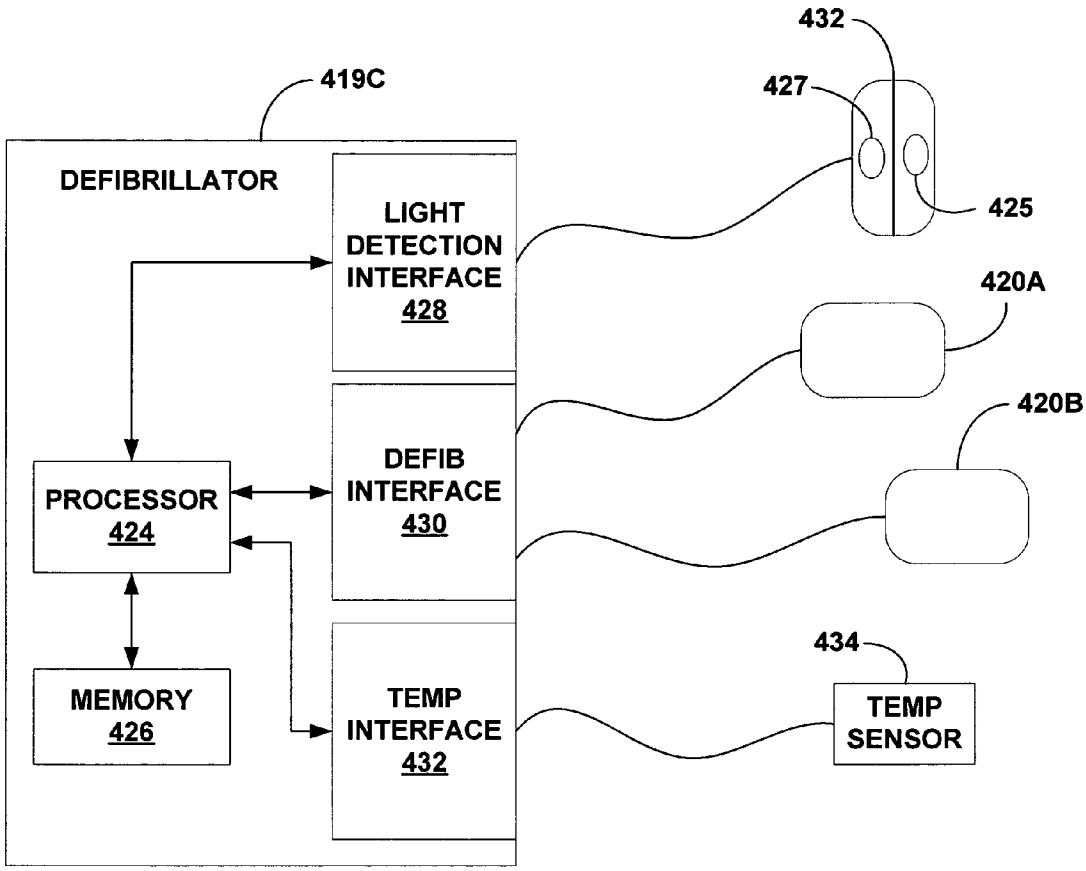

432
427
419C
DEFIBRILLATOR
LIGHT DETECTION INTERFACE 428
425
420A
420B
DEFIB INTERFACE 430
PROCESSOR 424
MEMORY 426
TEMP INTERFACE 432
434
TEMP SENSOR

FIG. 22

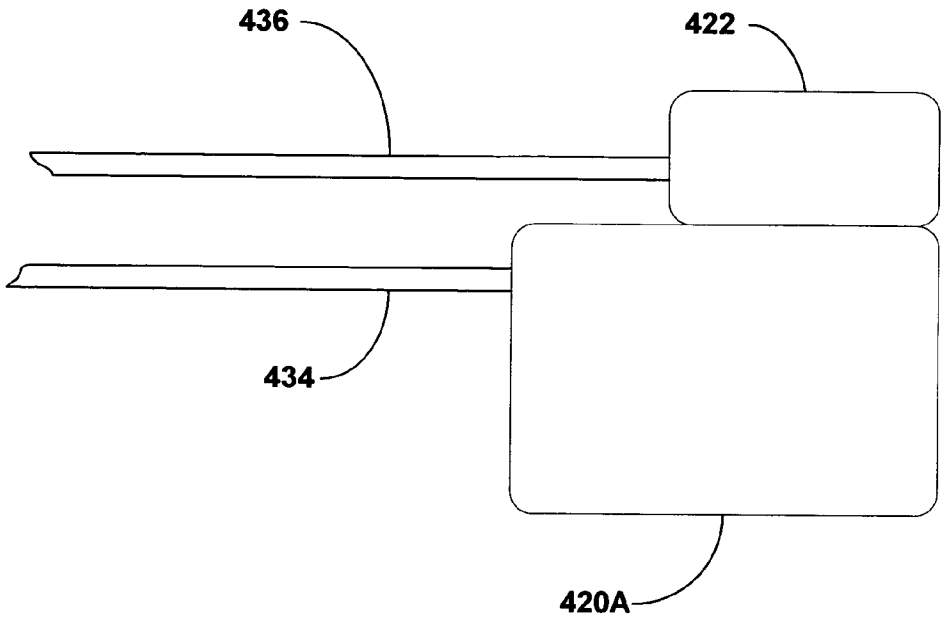


FIG. 23

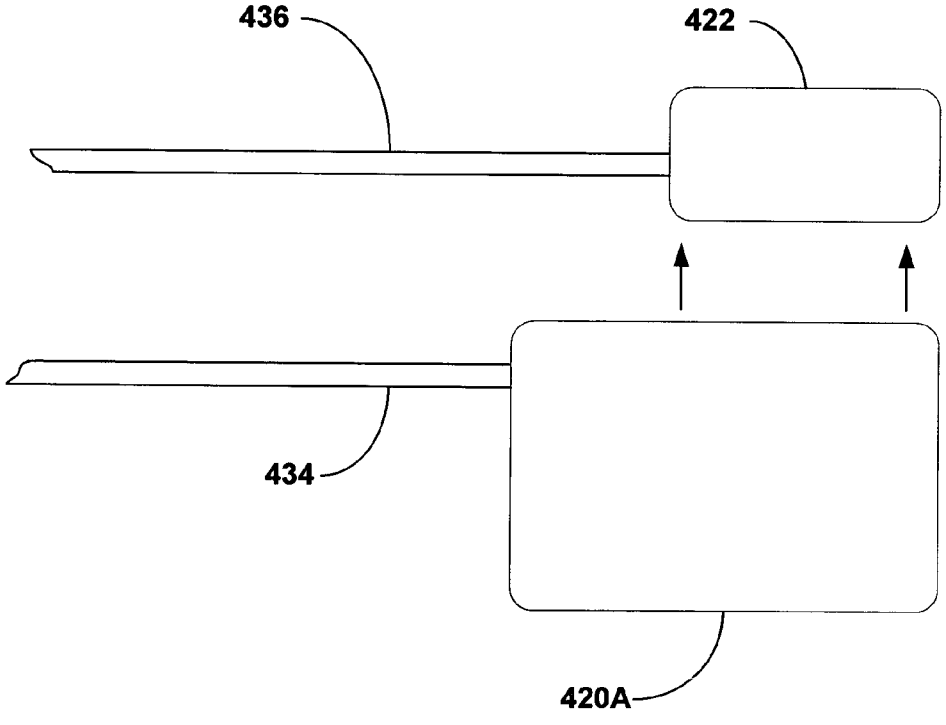


FIG. 24

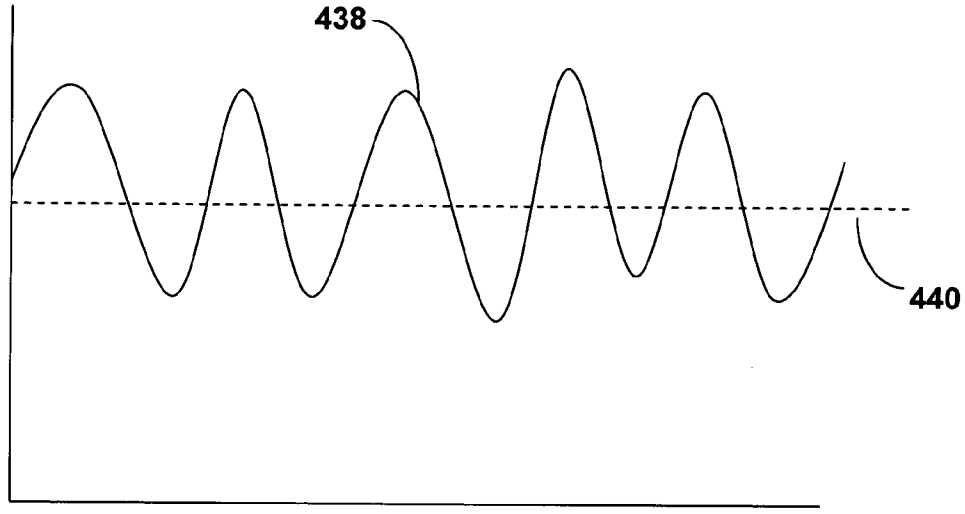


FIG. 25

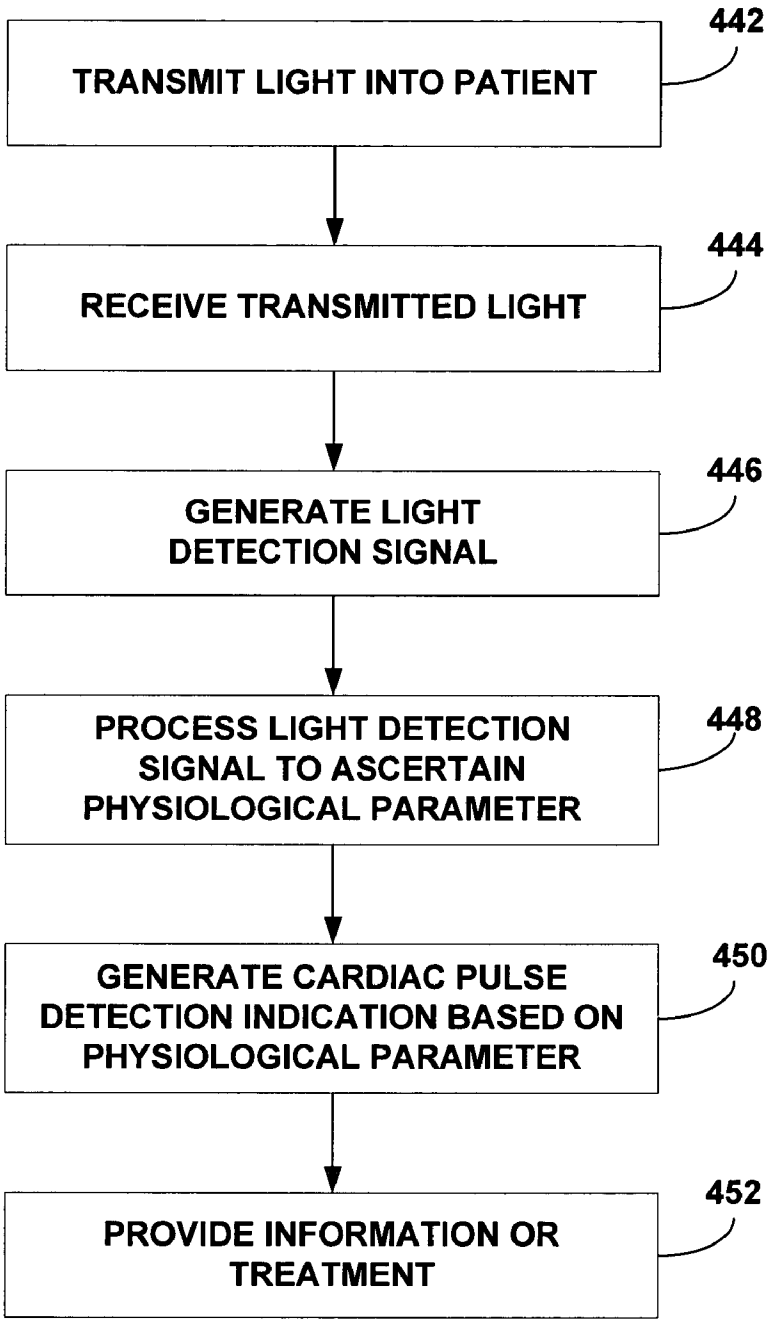

TRANSMIT LIGHT INTO PATIENT
442
RECEIVE TRANSMITTED LIGHT
444
GENERATE LIGHT DETECTION SIGNAL
446
PROCESS LIGHT DETECTION SIGNAL TO ASCERTAIN PHYSIOLOGICAL PARAMETER
448
GENERATE CARDIAC PULSE DETECTION INDICATION BASED ON PHYSIOLOGICAL PARAMETER
450
PROVIDE INFORMATION OR TREATMENT
452

FIG. 26

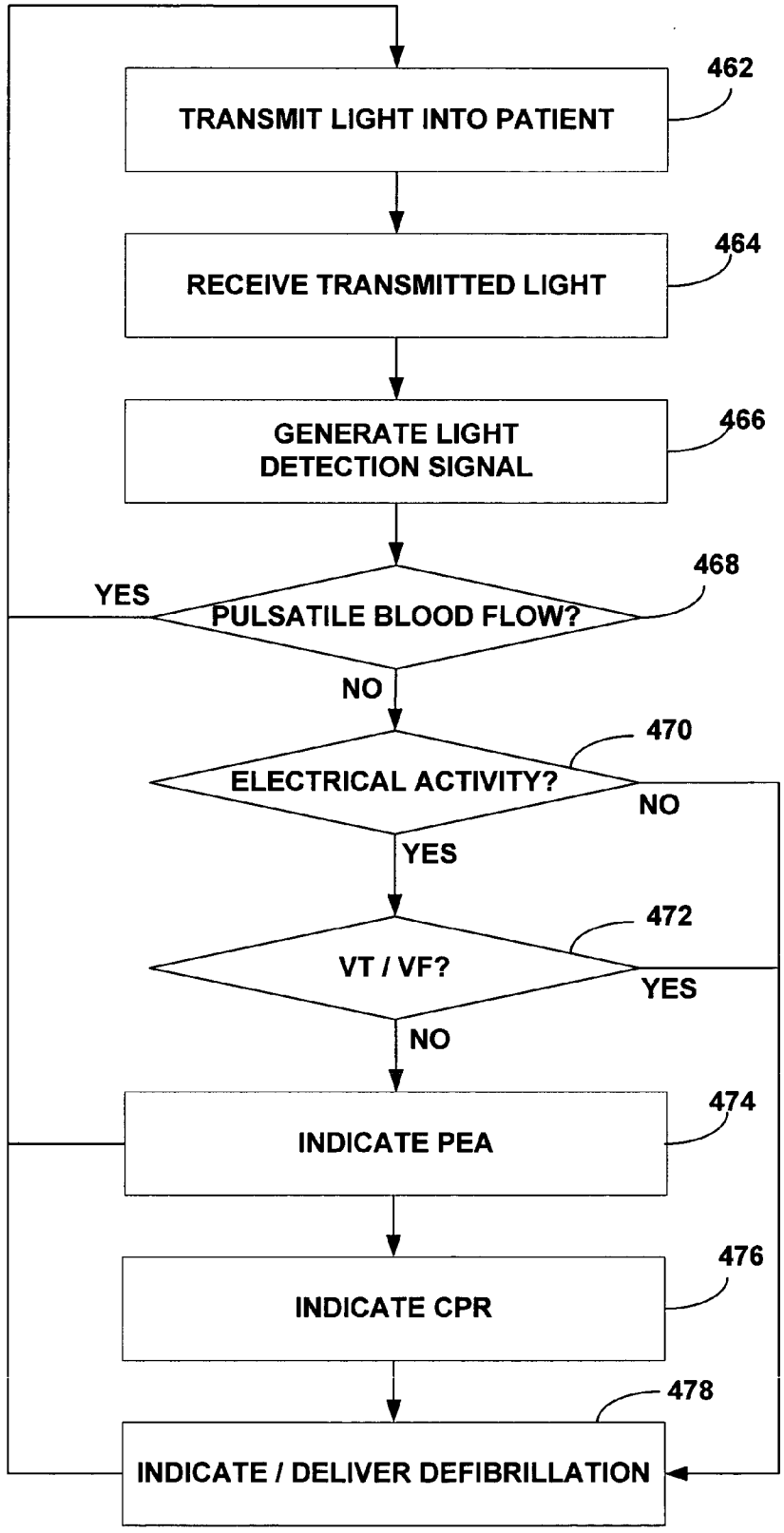

462
TRANSMIT LIGHT INTO PATIENT
464
RECEIVE TRANSMITTED LIGHT
466
GENERATE LIGHT DETECTION SIGNAL
468
YES
PULSATILE BLOOD FLOW?
NO
470
ELECTRICAL ACTIVITY?
NO
YES
472
VT / VF?
YES
NO
474
INDICATE PEA
476
INDICATE CPR
478
INDICATE / DELIVER DEFIBRILLATION

FIG. 27

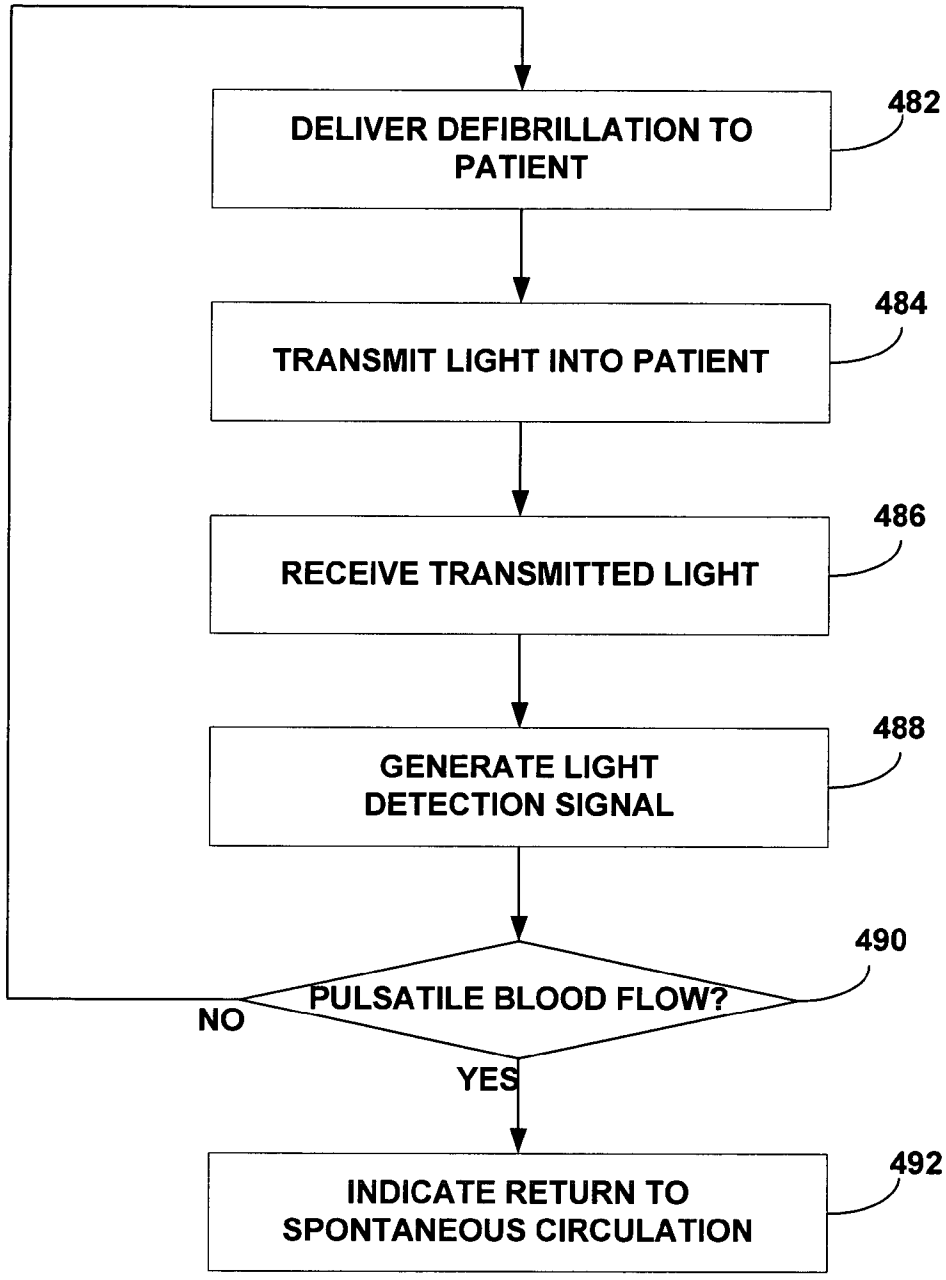

DELIVER DEFIBRILLATION TO PATIENT
482
TRANSMIT LIGHT INTO PATIENT
484
RECEIVE TRANSMITTED LIGHT
486
GENERATE LIGHT DETECTION SIGNAL
488
PULSATILE BLOOD FLOW?
490
NO
YES
INDICATE RETURN TO SPONTANEOUS CIRCULATION
492

FIG. 28

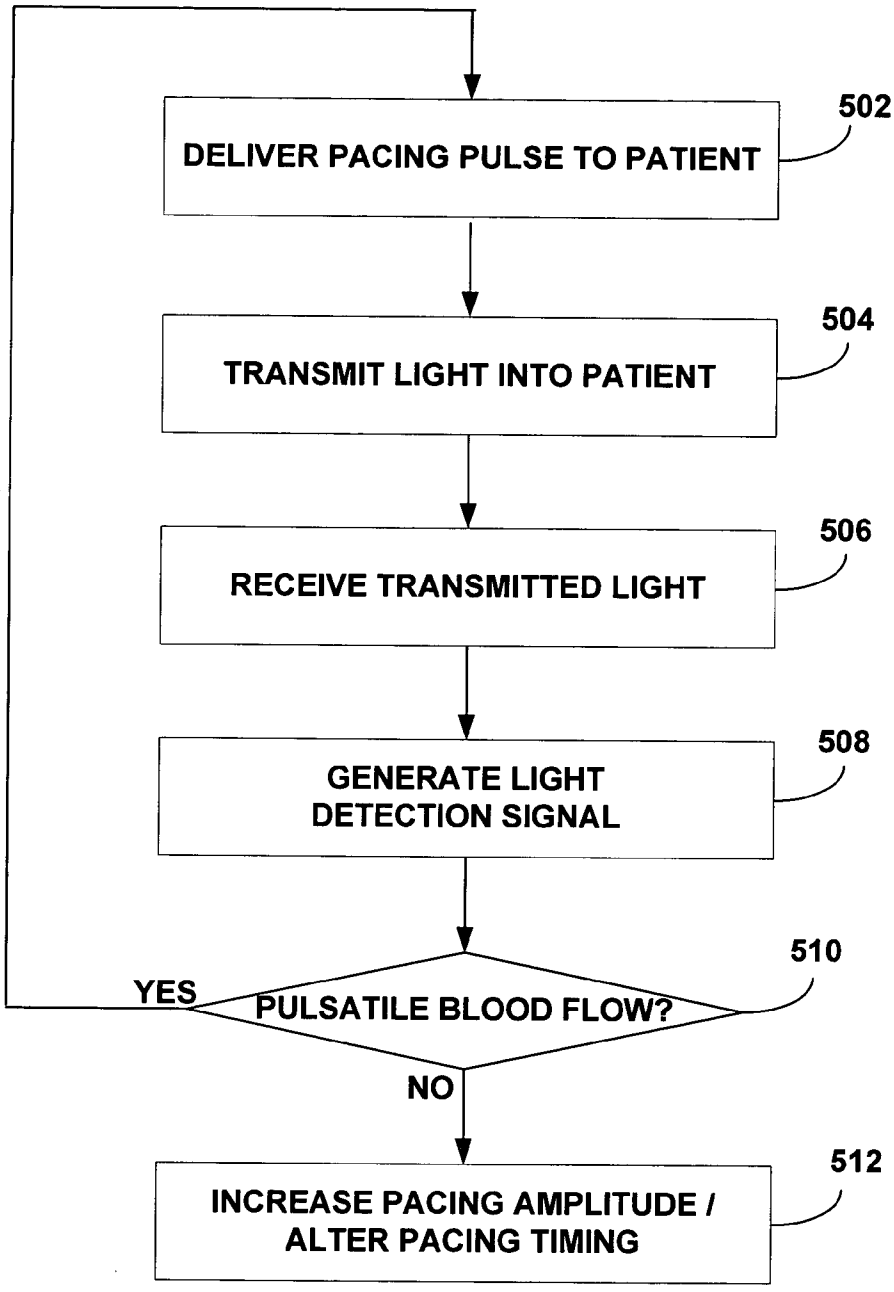

DELIVER PACING PULSE TO PATIENT
502
TRANSMIT LIGHT INTO PATIENT
504
RECEIVE TRANSMITTED LIGHT
506
GENERATE LIGHT DETECTION SIGNAL
508
PULSATILE BLOOD FLOW?
510
YES
NO
INCREASE PACING AMPLITUDE / ALTER PACING TIMING
512

FIG. 29

PULSE DETECTION USING PATIENT PHYSIOLOGICAL SIGNALS

[0001] This application is a continuation-in-part of U.S. application Ser. No. 10/229,320, filed Aug. 26, 2002, the entire content of which is incorporated herein by reference.

FIELD

[0002] The invention relates generally to the detection of cardiac activity in a patient, and more specifically, to the detection of a cardiac pulse and the use of pulse detection in delivering therapy.

BACKGROUND

[0003] The presence of cardiac pulse, or heartbeat, in a patient is generally detected by palpating the patient's neck and sensing changes in the volume of the patient's carotid artery due to blood pumped from the patient's heart. A graph representative of the physical expansion and contraction of a patient's carotid artery during two consecutive pulses, or heartbeats, is shown at the top of **FIG. 1**. When the heart's ventricles contract during a heartbeat, a pressure wave is sent throughout the patient's peripheral circulation system. The carotid pulse shown in **FIG. 1** rises with the ventricular ejection of blood at systole and peaks when the pressure wave from the heart reaches a maximum. The carotid pulse falls off again as the pressure subsides toward the end of each pulse.

[0004] The opening and closing of the patient's heart valves during a heartbeat causes high-frequency vibrations in the adjacent heart wall and blood vessels. These vibrations can be heard in the patient's body as heart sounds. A conventional phonocardiogram (PCG) transducer placed on a patient converts the acoustical energy of the heart sounds to electrical energy, resulting in a PCG waveform that may be recorded and displayed, as shown by the graph in the upper middle portion of **FIG. 1**. Conventional methods for detecting and displaying a PCG waveform are known in the art. See, e.g., U.S. Pat. Nos. 5,687,738 and 4,548,204.

[0005] As indicated by the PCG waveform shown in **FIG. 1, a** typical heartbeat produces two main heart sounds. The first heart sound, denoted **S1**, is generated by vibration generally associated with the closure of the tricuspid and mitral valves at the beginning of systole. Typically, the heart sound **S1** is about 14 milliseconds long and contains frequencies up to approximately 500 Hz. The second heart sound, denoted **S2**, is generally associated with vibrations resulting from the closure of the aortic and pulmonary valves at the end of systole. While the duration of the second heart sound **S2** is typically shorter than the first heart sound **S1**, the spectral bandwidth of the heart sound **S2** is typically larger than that of **S1**.

[0006] An electrocardiogram (ECG) waveform describes the electrical activity of a patient's heart. The graph in the lower middle portion of **FIG. 1** illustrates an example of an ECG waveform for two heartbeats and corresponds in time with the carotid pulse and PCG waveform. Referring to the first shown heartbeat, the portion of the ECG waveform representing depolarization of the atrial muscle fibers is referred to as the "P" wave. Depolarization of the ventricular muscle fibers is collectively represented by the "Q."R," and "S" waves of the ECG waveform. Finally, the portion of the waveform representing repolarization of the ventricular muscle fibers is known as the "T" wave. Between heartbeats, the ECG waveform returns to an isopotential level.

[0007] Fluctuations in a patient's transthoracic impedance also correlate with blood flow that occurs with each cardiac pulse wave. The bottom graph of **FIG. 1** illustrates an example of a filtered impedance signal for a patient in which fluctuations in impedance correspond in time with the carotid pulse, the PCG, and ECG waveforms.

[0008] The lack of a detectable cardiac pulse in a patient is a strong indicator of cardiac arrest. Cardiac arrest is a life-threatening medical condition in which the patient's heart fails to provide enough blood flow to support life. During cardiac arrest, the electrical activity may be disorganized (ventricular fibrillation), too rapid (ventricular tachycardia), absent (asystole), or organized at a normal or slow heart rate without sufficient blood flow (pulseless electrical activity).

[0009] A caregiver may apply a defibrillation shock to a patient in ventricular fibrillation (VF) or ventricular tachycardia (VT) to stop the unsynchronized or rapid electrical activity and allow a perfusing rhythm to return. External defibrillation, in particular, is provided by applying a strong electric pulse to the patient's heart through electrodes placed on the surface of the patient's body. If a patient lacks a detectable pulse but has an ECG rhythm of asystole or pulseless electrical activity (PEA), conventional therapy may include cardiopulmonary resuscitation (CPR), which causes some blood flow.

[0010] Before providing defibrillation therapy or CPR to a patient, a caregiver must first confirm that the patient is in cardiac arrest. In general, external defibrillation is suitable only for patients that are unconscious, apneic (i.e., not breathing), pulseless, and in VF or VT. Medical guidelines indicate that the presence or absence of a pulse in a patient should be determined within 10 seconds. See, "American Heart Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, Part 3: Adult Basic Life Support," Circulation 102 suppl. II-22-I-59, 2000.

[0011] Unfortunately, under the pressures of an emergency situation, it can be extremely difficult for first-responding caregivers with little or no medical training to consistently and accurately detect a cardiac pulse in a patient (e.g., by palpating the carotid artery) in a short amount of time such as 10 seconds. See, Eberle B., et al., "Checking the Carotid Pulse Diagnostic Accuracy of First Responders in Patients With and Without a Pulse" Resuscitation 33: 107-116, 1996.

[0012] Nevertheless, because time is of the essence in treating cardiac arrest, a caregiver may rush the preliminary evaluation, incorrectly conclude that the patient has no pulse, and proceed to provide therapy, such as defibrillation, when in fact the patient has a pulse. Alternatively, a caregiver may incorrectly conclude that the patient has a pulse and erroneously withhold defibrillation therapy. A need therefore exists for a method and apparatus that quickly, accurately, and automatically determines the presence of a pulse in a patient, particularly to prompt a caregiver to provide appropriate therapy in an emergency situation.

SUMMARY

[0013] The present invention provides methods and apparatus for determining the presence of a cardiac pulse in a

patient by evaluating physiological signals in the patient. In some embodiments, a medical device constructed according to the invention makes use of optical, i.e., light-based, techniques to ascertain one or more physiological signals indicative of a cardiac pulse. In particular, one or more physiological signals may be derived from analysis of a light detection signal generated by an light detection module. In other embodiments, physiological signals may he derived from different techniques. In each case, a processor is configured to evaluate the physiological signal for a feature indicative of the presence of a cardiac pulse. Using these features, the medical device determines whether a cardiac pulse is present in the patient. The medical device may further include a display that is used to automatically report whether a cardiac pulse is present in the patient. Exemplary embodiments of the invention discussed herein use physiological signals derived from light detection signals, phonocardiogram (PCG) signals, electrocardiogram (ECG) signals, and patient impedance signals. Also, as noted herein, embodiments of the invention may use signals obtained from piezoelectric sensors and/or accelerometers placed on the patient's body.

[0014] A feature indicating the presence of a pulse may be obtained from evaluation of temporal parameters or spectral parameters in the physiological signal data generated based on a light detection signal. In one aspect, temporal energy may be evaluated by estimating instantaneous and background energies in the signal data and comparing the instantaneous energy with the background energy. Energy in the signal data may also be calculated and compared with a threshold energy. In another aspect, spectral energy may be evaluated by locating a peak energy value in the energy spectrum and comparing the peak energy value with a threshold energy value. Alternatively, or in addition, the frequency of the peak energy value in the spectrum may be compared with a threshold frequency.

[0015] In embodiments of the invention that evaluate ECG data, a feature indicative of the presence of a cardiac pulse may be determined based at least in part on the presence of a ventricular complex, such as a QRS complex, in the ECG data. Moreover, the presence of a ventricular complex in the ECG data may be used to select time segments of data from one or more of the other physiological signals that correspond in time with the ventricular complex. Identifying and evaluating physiological signal data based on the presence of a ventricular complex helps focus the evaluation of the physiological signal data to that data which are more likely to indicate the presence of a pulse.

[0016] Features thus obtained from the physiological signal data are evaluated to determine whether a cardiac pulse is present in the patient. A medical device constructed in accordance with the invention may further include a defibrillation pulse generator that is configured to automatically prepare a defibrillation pulse for delivery to the patient if processing circuitry of the medical device determines that a cardiac pulse is not present in the patient. Alternatively, or in addition, the medical device may be configured to provide a message on its display prompting application of defibrillation electrodes to the patient if a cardiac pulse is determined not present. Further, a message may be displayed prompting delivery of chest compressions or cardiopulmonary resuscitation to the patient if a cardiac pulse is determined not present in the patient. A graph may be provided on the display showing a representation of at least one of the physiological signals obtained from the patient.

[0017] Another embodiment of the present invention is an electrotherapy device that includes electrodes adapted to sense a physiological signal, such as a PCG signal, in a patient. Processing circuitry in the electrotherapy device is configured to analyze the PCG signal for a feature indicative of the presence of a cardiac pulse and determine whether a cardiac pulse is present based on the feature. If a cardiac pulse is determined not present, the processing circuitry prompts the delivery of electrotherapy to the patient. Where the electrotherapy is defibrillation therapy, the processing circuitry may be configured to report the return of spontaneous circulation in the patient if a cardiac pulse is determined to be present after the delivery of the defibrillation therapy.

[0018] The electrotherapy device may further sense ECG signals in the patient and analyze the ECG signals for ventricular fibrillation (VF), ventricular tachycardia (VT), asystole, and pulseless electrical activity (PEA). In one aspect, if the patient is determined to be pulseless and experiencing ventricular tachycardia, the electrotherapy device may prompt the delivery of defibrillation therapy. In another aspect, if the patient is determined to be pulseless and not in a VF, VT, or asystole condition, the processing circuitry may prompt delivery of electrotherapy that is specifically designed for pulseless electrical activity. The processing circuitry may also be configured to report whether the patient is in a VF, VT, asystole, or PEA condition, in addition to being in a pulseless condition.

[0019] In a further embodiment of the invention, the electrotherapy device also includes electrodes adapted to receive an impedance-sensing signal that has been communicated through the patient. The PCG and impedance signals are each analyzed for features indicative of the presence of a cardiac pulse in the patient. The electrotherapy device uses these features to determine the presence of a cardiac pulse. The impedance signal may also be used to determine the presence of respiration in the patient. If respiration is determined not present in the patient, the processing circuitry may prompt delivery of rescue breathing. If the patient is also determined to be pulseless, the processing circuitry may prompt the delivery of chest compressions or full cardiopulmonary resuscitation.

[0020] Yet another embodiment of the present invention provides an apparatus and method for delivering electrotherapy to a patient in which the electrotherapy is comprised of pacing stimuli and seeks capture of a cardiac pulse in the patient. The method includes delivering a pacing stimulus to the patient, sensing a physiological signal in the patient from the surface of the patient's body, determining whether a cardiac pulse occurred in the patient after delivery of the pacing stimulus, and increasing the current of further pacing stimuli to be delivered to the patient if a cardiac pulse did not occur in the patient after delivery of the pacing stimulus. For example, the physiological signal may be a PCG signal that is analyzed for the presence of a heart sound, the electrotherapy device determining whether a cardiac pulse occurred in the patient based on the presence of a heart sound. Consistent capture exhibited by a cardiac pulse may be required before making a final determination that capture of a cardiac pulse has been achieved.

[0021] In another embodiment, the invention provides a method comprising transmitting light into a patient, receiving light that has been transmitted into the patient, generating a light detection signal in response to the received light, processing the light detection signal over a period of time to detect a trend in pulsatile changes in blood volume, and providing at least one of treatment and information concerning treatment based on the trend in pulsatile changes blood volume.

[0022] In a further embodiment, the invention provides a method comprising transmitting first light into a patient at a first wavelength, transmitting second light into a patient at a second wavelength, receiving the first and second light that has been transmitted into the patient, generating a light detection signal in response to the received light, and processing the light detection signal over a period of time to detect a physiological parameter indicative of a cardiac pulse.

[0023] In an added embodiment, the invention provides a medical device comprising a light source to transmit light into a patient, a sensor to receive light that has been transmitted into the patient, a circuit to generate a light detection signal in response to the received light, and a processor to process the light detection signal over a period of time to detect a trend in pulsatile changes in the flow of blood, and provide at least one of treatment and information concerning treatment based on the trend in pulsatile changes blood volume.

[0024] In another embodiment, the invention provides a medical device comprising a light source to transmit a first light into a patient at a first wavelength and a second light into the patient at a second wavelength, a sensor to receive the first and second light that has been transmitted into the patient, a circuit to generate a light detection signal in response to the received light, a processor to process the light detection signal to detect a physiological parameter indicative of presence of a cardiac pulse, and provide at least one of treatment and information concerning treatment based on physiological parameter.

[0025] In a further embodiment, the invention provides a method comprising applying a defibrillation electrode with a pulse detector to a first position of a patient, performing a first pulse detection, detaching the pulse detector from the defibrillation electrode, placing the detached pulse detector at a second position of the patient, and performing a second pulse detection.

[0026] In another embodiment, the invention provides a medical device comprising a defibrillation electrode, and a pulse detector detachably coupled to the defibrillation electrode.

[0027] In an added embodiment, the invention provides a a medical device comprising defibrillation electrode; and a light source for a pulse detector embedded in the defibrillation electrode.

[0028] In a further embodiment, the invention provides a method comprising transmitting light into a patient at a first intensity, receiving light transmitted into the patient at the first intensity to generate a first light detection signal, transmitting light into the patient at a second intensity, receiving light transmitted into the patient at the second intensity to generate a second light detection signal, processing the light detection signals to detect a physiological parameter indicative of presence of a cardiac pulse, and providing at least one of treatment and information concerning treatment based on the physiological parameter.

[0029] In another embodiment, the invention provides a medical device comprising a light source that transmits light into a patient at a first intensity and a second intensity, a light detector that receives light transmitted into the patient at the first intensity to generate a first light detection signal, and receives light transmitted into the patient at the second intensity to generate a second light detection signal, and a processor that processes the light detection signals to detect a physiological parameter indicative of presence of a cardiac pulse, and provides at least one of treatment and information concerning treatment based on the physiological parameter.

[0030] The invention further contemplates medical devices capable of implementing the foregoing methods, as well as computer-readable media storing instructions sufficient to cause a processor to implement various aspects of the methods.

[0031] Other applications and advantages of the present invention are apparent. For example, the invention may be implemented in an automated external defibrillator (AED). Embodiments of the invention intended for trained medical personnel may provide additional displays of the patient's physiological signal data for review.

[0032] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0033] **FIG. 1** is a pictorial diagram of a carotid pulse waveform, a phonocardiogram (PCG) waveform, an electrocardiogram (ECG) waveform, and a filtered transthoracic impedance signal for two consecutive heartbeats.

[0034] **FIG. 2** is a pictorial diagram of a defibrillator and electrodes constructed in accordance with the present invention and attached to a patient.

[0035] **FIG. 3** is a block diagram of the major components of a defibrillator as shown in **FIG. 2**.

[0036] **FIG. 4** is a flow diagram of a pulse detection process performed by a defibrillator as shown in **FIG. 2**, in which a temporal energy analysis of PCG data is performed.

[0037] **FIG. 5A** is a graph illustrating a PCG waveform of raw PCG data collected from a patient.

[0038] **FIG. 5B** is a graph illustrating a filtered version of the PCG waveform shown in **FIG. 5A**.

[0039] **FIG. 5C** is a graph illustrating an instantaneous energy waveform and the background energy waveform computed from the data in the PCG waveform shown in **FIG. 5B** in accordance with the pulse detection process shown in **FIG. 4**.

[0040] **FIG. 5D** is a graph illustrating the results of a comparison of the instantaneous energy and the background energy shown in **FIG. 5C** in accordance with the pulse detection process shown in **FIG. 4**.

[0041] **FIG. 6** is a flow diagram of another pulse detection process performed by a defibrillator as shown in **FIG. 2**, in which a spectral peak frequency analysis of PCG data is performed.

[0042] **FIG. 7** is a graph illustrating two energy spectra calculated from PCG data using a maximum entropy method ("NMM spectra") in accordance with the pulse detection process shown in **FIG. 6**.

[0043] **FIG. 8A** is a graph illustrating a PCG waveform of raw PCG data collected from a patient.

[0044] **FIG. 8B** is a graph illustrating a series of frequencies of second peak energy values located in MEM spectra computed in accordance with the pulse detection process shown in **FIG. 6** using the PCG data shown in **FIG. 8A**, in which the frequency values at or below a frequency of 100 Hz are marked with an "x".

[0045] **FIG. 8C** is a graph illustrating a series of second peak energy values located in MEM spectra computed in accordance with the pulse detection process shown in **FIG. 9** using the PCG data shown in **FIG. 8A**, in which the second peak energy values exceeding 0 dB are marked with an "x".

[0046] **FIG. 9** is a flow diagram illustrating another pulse detection process performed by a defibrillator as shown in **FIG. 2**, in which a spectral peak energy analysis is performed.

[0047] **FIG. 10** is a flow diagram illustrating yet another pulse detection process performed by a defibrillator as shown in **FIG. 2** that incorporates features of the pulse detection processes shown in **FIGS. 4, 6** and **9**.

[0048] **FIG. 11** is a flow diagram of a pulse detection process performed by a defibrillator as shown in **FIG. 2**, in which an analysis of impedance signal data is performed.

[0049] **FIG. 12** is a flow diagram of a pulse rate analysis performed with the pulse detection process shown in **FIG. 11**.

[0050] **FIG. 13** is a flow diagram of another pulse detection process performed in accordance with the present invention in which an impedance signal pattern analysis is performed without an ECG signal analysis.

[0051] **FIG. 14** is a flow diagram of a pulse detection process of the present invention that analyzes multiple physiological signals, in this case impedance and heart sound signals, to determine the presence of a cardiac pulse.

[0052] **FIG. 15** is a flow diagram of a procedure implemented by a defibrillator as shown in **FIG. 2** that incorporates a pulse detection process provided by the present invention.

[0053] **FIG. 16** is a flow diagram of another procedure implemented by a defibrillator as shown in **FIG. 2** that incorporates a pulse detection process provided by the present invention.

[0054] **FIG. 17** is a flow diagram of still another procedure implemented by a defibrillator as shown in **FIG. 2** that incorporates a pulse detection process provided by the present invention.

[0055] **FIG. 18** is a flow diagram of an auto-capture detection process for cardiac pacing that uses a pulse detection process of the present invention.

[0056] **FIG. 19** is a flow diagram of a patient condition advisory process for use in a medical device that incorporates a pulse detection process of the present invention.

[0057] **FIG. 20** is a block diagram of a defibrillator incorporating an optical pulse detector with multiple light sources.

[0058] **FIG. 21** is a block diagram illustrating a defibrillator incorporating an optical pulse detector with a single light source.

[0059] **FIG. 22** is a block diagram of a defibrillator incorporating an optical pulse detector and a temperature sensor.

[0060] **FIG. 23** is a diagram of a defibrillator incorporating an optical pulse detector with an optical pulse detector attached to a defibrillation electrode.

[0061] **FIG. 24** is a block diagram of a defibrillator incorporating an optical pulse detector that is detachable from a defibrillation electrode.

[0062] **FIG. 25** is a graph illustrating a light detection signal with a dc component.

[0063] **FIG. 26** is a flow diagram illustrating a technique for cardiac pulse detection based on a light detection signal.

[0064] **FIG. 27** is a flow diagram illustrating an exemplary operation of a medical device to indicate conditions of a patient or therapy to be delivered to the patient based on the absence of pulsatile blood flow as detected via an optical pulse detector.

[0065] **FIG. 28** is a flow diagram illustrating an exemplary operation of a medical device to report the return of spontaneous circulation (ROSC) in a patient after delivery of a defibrillation shock to the patient.

[0066] **FIG. 29** is a flow diagram illustrating an exemplary operation of a medical device to deliver pacing therapy to a patient.

DETAILED DESCRIPTION

[0067] The present invention may be implemented in a variety of applications. One particular implementation of the present invention is a defibrillator as illustrated in **FIG. 2**. In **FIG. 2**, the defibrillator **10** is shown connected to a patient **24** via defibrillation electrodes **12** and **14** placed on the skin of the patient **24**. The defibrillator **10** uses the defibrillation electrodes **12** and **14** to deliver defibrillation pulses to the patient **24**. The defibrillator **10** may also use the electrodes **12** and **14** to obtain ECG signals from the patient **24**.

[0068] **FIG. 2** further illustrates sensing devices **16** and **18** placed on the patient **24**. The sensing devices **16** and **18** are configured to detect a physiological signal in the patient, such as acoustical energy from heart sounds produced in the patient **24** or electrical energy that reflects a patient characteristic such as transthoracic impedance. In one exemplary embodiment discussed herein, the sensing devices **16** and **18** are configured to detect acoustical energy while the defibrillation electrodes **12** and **14** are used for assessing patient impedance. Acoustical energy sensed by the devices **16** and **18** is converted by the defibrillator **10** into digital phonocardiogram (PCG) data. In other embodiments described herein, optical, i.e., light based techniques, can be used to detect cardiac pulses.

[0069] The sensing devices **16** and **18** may be integrated into or attached to the back of the electrodes **12** and **14**. Alternatively, the sensing devices **16** and **18** may be embodied in flaps **20** and **22** that are connected to the electrodes **12** and **14**. As another alternative, the sensing devices **16** and **18** may be attached to the patient **24** by separate wires (not shown).

[0070] In one embodiment of the invention, the sensing devices **16** and **18** are comprised of transducers with a piezoelectric membrane. The sensing devices **16** and **18** may alternatively be comprised of acoustic sensors known in the art, such as electronic microphones used in stethoscopes. Transducers and/or microphones suitable for use in the present invention for detecting heart sounds are described, for example, in U.S. Pat. Nos. 4,446,873 and 5,825,895.

[0071] A device constructed in accordance with the present invention may also use measurements of a patient's transthoracic impedance, separately or in connection with detecting heart sounds, to determine the presence of a cardiac pulse in a patient. In that regard, the electrodes **12**, **14** may be configured to communicate an impedance-sensing signal through the patient **24**. The impedance-sensing signal is used by the defibrillator **10** to measure the patient's impedance.

[0072] A preferred embodiment of the invention uses a high-frequency, low-level constant current technique to measure the patient's transthoracic impedance, though other known impedance measuring techniques may be used. A signal generator included in the defibrillator **10** produces a low-amplitude, constant current, high-frequency signal (typically sinusoidal or square). The signal is preferably generated having a frequency in the range of 10 kHz-100 kHz and causes a current to flow between the electrodes **12** and **14**. The current flow causes a voltage to develop across the patient's body that is proportional to the product of the patient's impedance and the applied current. To calculate the patient's impedance, the impedance measuring component in the defibrillator **10** divides the measured sensing voltage by the applied current. Of course, since the measured voltage is linearly related to the patient's impedance, the impedance signal data used herein may be a calculated impedance signal or the measured voltage signal.

[0073] While embodiments of the invention specifically described herein are shown implemented in a defibrillator **10**, the present invention is not limited to such specific type of application. Those of ordinary skill in the art will recognize that the advantages of the invention may similarly be achieved by implementing the present invention in cardiac monitors and other types of medical equipment that do not necessarily provide defibrillation therapy.

[0074] Prior to discussing various pulse detection processes that the defibrillator **10** may implement in accordance with the present invention, a brief description of certain major components of the defibrillator **10** is provided. Referring to **FIG. 3**, the defibrillator **10** includes defibrillation electrodes **30** (e.g., electrodes **12**, **14** described above in **FIG. 2**). An impedance-sensing signal generator **56** communicates an impedance-sensing signal through the patient via the electrodes **30**. A signal amplifier **32** receives the impedance-sensing signal from the electrodes **30** and amplifies the signal to a level appropriate for digitization by analog-to-digital (A/D) converter **36**. Prior to AID conversion, a bandpass filter **34** filters the amplified impedance-sensing signal to isolate the portion of the signal that most closely reveals fluctuations due to blood flow from cardiac pulses. In one embodiment of the invention, the bandpass filter **34** is a 1-10 Hz bandpass filter. Fluctuations in the impedance signal below 1 Hz are believed more likely to be caused by respiration in the patient, and not blood flow. Accordingly, the bandpass filter attenuates that component of the impedance signal. The portion of the impedance signal exceeding 10 Hz is believed more likely affected by surrounding noise and is likewise filtered out.

[0075] The filtered impedance signal is delivered to the A/D converter **36** which converts the impedance signal into digital impedance data for further evaluation. The bandpass filter **34** or other filter may be provided to reduce any aliasing introduced in the impedance signal by the A/D converter **36**. The parameters of such filtering depend, in part, on the sampling rate of the A/D converter. Bandpass and antialiasing filters, as well as A/D converters, are well-known in the art, and may be implemented in hardware or software, or a combination of both. For example, a preferred embodiment uses a hardware lowpass filter on the impedance signal before the A/D converter **36**, and then a software highpass filter on the digital impedance data after the AID conversion. Another preferred embodiment additionally uses a software lowpass filter after the A/D conversion to further limit the bandwidth of the impedance signal. The AID converter **36** delivers the digital impedance signal data to a processing circuit **38** for evaluation.

[0076] The processing circuit **38** evaluates the impedance signal data for the presence of a cardiac pulse. The processing circuit **38** is preferably comprised of a computer processor that operates in accordance with programmed instructions stored in a memory **40** that implement a pulse detection process **42**, described in more detail below. The processing circuit **38** may also store in the memory **40** the impedance signal data obtained from the patient, along with other event data and ECG signal data. The memory **40** may be comprised of any type or combination of types of storage medium, including, for example, a volatile memory such as a dynamic random access memory (DRAM), a non-volatile static memory, or compute-readable media such as a magnetic tape or disk or optical storage unit (e.g., CD-RW or DVD) configured with permanent or removable media.

[0077] The processing circuit **38** may report the results of the pulse detection process to the operator of the defibrillator **10** via a display **48**. The processing circuit **38** may also prompt actions (e.g., CPR) to the operator to direct the resuscitation effort. The display **48** may include, for example, lights, audible signals, alarm, printer, tactile response, and/or display screen. The processing circuit **38** may also receive input from the operator of the defibrillator **10** via an input device **46**. The input device **46** may include one or more keys, switches, buttons, dials, or other types of user input devices.

[0078] The defibrillator **10** shown in **FIG. 3** is also capable of sensing a patient's heart sounds using PCG electrodes **26** (e.g., sensing devices **16** and **18**, as described above in reference to **FIG. 2**). The PCG electrodes **26** provide the sensed heart sound signals, or PCG signals, to a signal amplifier **28** that amplifies the PCG signals to a level sufficient for the defibrillator **10** to further analyze the PCG signals.

[0079] The signal amplifier **28** provides the amplified PCG signals to an anti-aliasing filter **29**. The anti-aliasing filter **29** is designed to reduce aliasing introduced in the PCG signals by the analog-to-digital (A/D) converter **36**. The bandwidth of the anti-aliasing filter **29** depends, in part, on the sampling rate of the A/D converter **36**. Anti-aliasing filters and AID converters are well-known in the art and are readily available in off-the-shelf devices. Alternative embodiments of the defibrillator **10** may include additional signal amplification or signal filtering to adapt the defibrillator **10** for use in particular environments.

[0080] The A/D converter **36** converts the PCG signals into digitized PCG data and provides the PCG data to the processing circuit **38** for evaluation. The processing circuit **38** evaluates the PCG data using a pulse detection process described below in more detail. Programmed instructions **42** stored in the memory **40** may be used to implement the pulse detection process. Preferably, the processing circuit **38** also stores the PCG data in the memory **40**.

[0081] The defibrillation electrodes **30** may further be used to sense the patient's electrocardiogram (ECG) signals. ECG signals obtained from the patient are amplified by the ECG signal amplifier **52** and filtered by the ECG bandpass filter **54** in a conventional manner. The A/D converter **36** converts the ECG signals into digitized ECG data and provides the ECG data to the processing circuit **38** for evaluation.

[0082] Preferably, the processing circuit **38** evaluates the ECG signals in accordance with programmed instructions **44** stored in the memory **40** that carry out an ECG evaluation process to determine whether a defibrillation shock should be provided. A suitable method for determining whether to apply a defibrillation shock is described in U.S. Pat. No. 4,610,254, which is assigned to the assignee of the present invention and incorporated by reference herein. If the processing circuit **38** determines that immediate delivery of a defibrillation pulse is appropriate, the processing circuit **38** instructs a defibrillation pulse generator **50** to prepare to deliver a defibrillation pulse to the patient. In that regard, the defibrillation pulse generator **50** uses an energy source (e.g., a battery) to charge one or more defibrillation capacitors in the defibrillator **10**.

[0083] When the defibrillation charge is ready for delivery, the processing circuit **38** advises the operator via the display **48** that the defibrillator **10** is ready to deliver the defibrillation pulse. The processing circuit **38** may ask the operator to initiate the delivery of the defibrillation pulse. When the operator initiates delivery of the defibrillation pulse (e.g., via the input device **46**), the processing circuit **38** instructs the defibrillation pulse generator **50** to discharge through the patient the energy stored in the defibrillation capacitors (via the defibrillation electrodes **30**). Alternatively, the processing circuit **38** may cause the defibrillation pulse generator **50** to automatically deliver the defibrillation pulse when specified conditions (e.g., expiration of a predetermined period of time, acceptable measured patient impedance, etc.) are met.

[0084] In some circumstances, it may be preferable to apply CPR to the patient before defibrillation even though cardiac conditions, such as VF, are detected, especially for patients in whom defibrillation is initially unlikely to succeed. See L. Cobb et al., "Influence of Cardiopulmonary Resuscitation Prior to Defibrillation in Patients With Out-of-Hospital Ventricular Fibrillation" JAMA 281:1182-1188 (1999), incorporated by reference herein. Thus, if desired, the defibrillator **10** may recommend the application of chest compressions or CPR in situations where a cardiac pulse is not detected and the ECG reveals a cardiac rhythm for which immediate treatment by defibrillation therapy is not indicated.

[0085] While **FIG. 3** illustrates certain major components of the defibrillator **10**, those having ordinary skill in the art will appreciate that the defibrillator **10** may contain more or fewer components than those shown. The disclosure of a preferred embodiment of the defibrillator **10** does not require that all of these general conventional components be shown. It will further be appreciated that aspects of the invention may be implemented in a cardiac monitor having essentially the same components as the defibrillator **10** shown in **FIG. 3**, except that the cardiac monitor does not have the components necessary for delivering a defibrillation pulse. Furthermore, some or all of the programmed instructions **44** may be implemented in hardware as an alternative to software instructions stored in the memory **40**.

[0086] In one aspect, the pulse detection process conducted by the processing circuit **38** may analyze the patient's PCG data to determine whether heart sounds **S1** and/or **S2** are present. The presence of heart sounds **S1** and/or **S2** are used as an indication of the presence of a cardiac pulse in the patient. In another aspect, the pulse detection process may analyze the patient's impedance signal data to determine the presence of a cardiac pulse. The pulse detection process preferably uses a portion of the impedance-sensing signal whose frequency range is most likely to reveal fluctuations indicating the presence of a cardiac pulse in the patient. Characteristic fluctuations in patient impedance associated with a cardiac pulse are used as an indication of the presence of a cardiac pulse. In yet another aspect, the pulse detection process may analyze multiple physiological signals. For example, the pulse detection process may analyze both PCG data for heart sounds and impedance signal data for characteristic fluctuations in a combined manner to determine the presence of a cardiac pulse.

[0087] **FIG. 4** illustrates a pulse detection process **60***a* that analyzes a temporal energy in the PCG data. The pulse detection process **60***a* begins at block **70** by obtaining PCG data from a patient. As noted earlier, PCG signals received from PCG sensing devices (e.g., sensing devices **16** and **18** in **FIG. 2**) placed on the patient are converted into digital PCG data.

[0088] The pulse detection process **60***a* evaluates the PCG data for at least one feature indicative of the presence of a heart sound. In blocks **72** and **74**, the pulse detection process **60***a* preferably calculates estimates of the instantaneous energy and background energy in the PCG data. As shown in **FIG. 4**, the estimated instantaneous energy may be calculated in block **72** simultaneously with the calculation of estimated background energy in block **74**. Alternatively, the calculation of estimated instantaneous energy in block **72** may be performed prior to or after the calculation of estimated background energy in block **74**.

[0089] The estimated instantaneous energy is calculated in block **72**, preferably using a set of PCG data obtained from the patient during a predetermined time window. One exemplary embodiment of the invention uses a time window of 20

milliseconds in length, though a longer, shorter, or shifted time window may be used for estimating the instantaneous energy. The estimated instantaneous energy may be calculated by squaring and summing each of the PCG data values in the predetermined time window.

[0090] The estimated background energy is calculated in block **74**, preferably using a set of PCG data obtained in an earlier predetermined time window. One exemplary embodiment of the invention calculates the estimated background energy using PCG data in a 100 millisecond time window commencing 220 milliseconds prior to the current time. The PCG data within the earlier time window may also be squared and summed to produce the estimated background energy. Furthermore, other time window lengths and starting points may be used.

[0091] The estimated instantaneous energy and background energy are next compared at block **76** to determine a relative change in energy in the PCG data. The relative change in energy is used by the pulse detection process **60***a* as a feature indicative of the presence of a heart sound. If the relative change in energy between the estimated instantaneous energy and the estimated background energy exceeds a predetermined threshold, the pulse detection process **60***a* determines that a heart sound was detected. Note that the background and instantaneous energies should previously be normalized for purposes of comparison to each other. For example, if squaring and summing is used and one energy uses a 100 ms time window and the other energy uses a 20 ms time window, the result of the energy using a 100 ms time window should be divided by 5 so it can be properly compared against the result from a 20 ms time window.

[0092] As discussed earlier, the present invention uses the detection of a heart sound as an indication of the presence of a cardiac pulse in the patient. In decision block **78**, if a heart sound was detected, the pulse detection process **60***a* proceeds to block **80** and reports the presence of a cardiac pulse in the patient (thus indicating that defibrillation therapy for the patient is not advised). Otherwise, if a heart sound is not detected, the pulse detection process **60***a* determines in block **82** that the patient is pulseless and that defibrillation therapy may be appropriate. A defibrillator **10** implementing the pulse detection process **60***a* may then proceed to determine whether defibrillation therapy is appropriate, e.g., by obtaining and processing ECG data from the patient as described in U.S. Pat. No. 4,610,254, referenced earlier and incorporated herein by reference.

[0093] In a further embodiment of the invention, the pulse detection process **60***a* may be repeated over a specified time interval or for a specified number of repetitions to produce a series of determinations of whether a heart sound is present in the patient. The time windows for computing the estimated instantaneous energy and background energy are shifted to correspond with each instance of time in which the pulse detection process **60***a* is performed. The pulse detection process **60***a* may require a specified number of heart sound detections before determining that a cardiac pulse is present in the patient.

[0094] FIGS. **5**A-**5**D illustrate a representative example of the processing performed by the pulse detection process **60***a*. In particular, **FIG. 5A** is a graph showing a PCG waveform **84** of raw PCG data as collected in block **70** (**FIG. 4**) from a patient. As noted above, the PCG data may be filtered to reduce noise and other signal contaminants. A filtered version of the PCG waveform **86** is shown in **FIG. 5B**.

[0095] **FIG. 5C** illustrates a waveform **88** depicting an estimated instantaneous energy in the PCG as calculated in block **72** of the pulse detection process **60***a*. The waveform **90** depicts an estimated background energy as calculated in block **74** of the pulse detection process **60***a*. Because the calculation of background energy **90** uses PCG data obtained in an earlier time window than the PCG data used to calculate instantaneous energy **88**, the rise and fall of the background energy waveform **90** follows the rise and fall of the instantaneous energy waveform **88**.

[0096] The comparison performed in block **76** of the pulse detection process **60***a* may produce a result as illustrated in **FIG. 5D**. During the time in which the instantaneous energy **88** exceeds the background energy **90** by a predetermined threshold, the comparison performed in block **76** returns a "1" (signifying the detection of a heart sound), as noted by reference numeral **92**. The predetermined threshold may be adjusted to achieve a desired sensitivity and specificity of detection. When the relative change in energy between the instantaneous energy **88** and the background energy **90** does not exceed the predetermined threshold, the comparison performed in block **76** returns a "0", as noted by reference number **94**, signifying that a heart sound was not detected.

[0097] **FIG. 6** illustrates another pulse detection process **60***b*. As with the detection process **60***a*, the detection process **60***b* analyzes PCG data to detect heart sounds in a patient. The detection process **60***b*, however, focuses on a spectral energy analysis of the PCG data (as compared to the temporal energy analysis performed in the detection process **60***a*).

[0098] The pulse detection process **60***b* begins at block **100** by obtaining PCG data from the patient in a manner as discussed above with respect to block **70** (**FIG. 4**). In block **102**, the PCG data is preferably analyzed to identify a set of PCG data that likely contains an **S1** or **S2** heart sound. In that regard, an **S1** or **S2** heart sound candidate may be identified by using the temporal energy comparison discussed in block **76** of the pulse detection process **60***a*. When the estimated instantaneous energy exceeds the estimated background energy by a predetermined threshold, the energy comparison suggests that a potential **S1** or **S2** candidate has been detected. Alternatively, a set of PCG data containing a heart sound may be identified by evaluating the patient's ECG data for the occurrence of an R-wave. The timing of an **S1** or **S2** heart sound in relation to an R-wave is generally known in the art and may be used to predict the timing of a heart sound candidate in the PCG data. Other embodiments of the invention may compute an energy spectrum without first identifying candidate PCG data, e.g., by continuously computing an energy spectrum using the most current PCG data as the candidate data.

[0099] Next, in block **104**, the pulse detection process **60***b* computes an energy spectrum of the heart sound candidate, preferably using a maximum entropy method, though other spectral calculations may be used. Computing an energy spectrum using a maximum entropy method ("MEM spectrum") is well-known in the art. See, e.g., Modern Spectral Estimation: Theory and Application, by Stephen M. Kay, published by Prentice Hall of Englewood Cliffs, N.J., begin-

ning at p. 182, and incorporated herein by reference. An MEM spectrum typically appears much smoother than an energy spectrum produced by Fourier transform techniques.

[0100] **FIG. 7** illustrates a representative MEM spectrum **120** for an interval of PCG data containing an **S1** heart sound. **FIG. 7** also illustrates a representative MEM spectrum **130** for a set of PCG data containing an **S2** heart sound. The MEM spectrum **120** includes a number of peak energy values, including the first two peak values **122** and **124**. Likewise, the MEM spectrum **130** includes a number of peak energy values, including the first two peak values **132** and **134**. The MEM spectrum **120** or **130**, whichever is used, may be normalized by removing a baseline (e.g., DC) energy value across the MEM spectrum.

[0101] As discussed below in more detail, the frequency of a peak energy value in the energy spectrum is used as-a feature indicative of the presence of a heart sound, and is evaluated against a predetermined threshold frequency value to decide whether a heart sound is detected. The pulse detection process **60***b* shown in **FIG. 6** evaluates the second peak energy value occurring in the energy spectrum measured from DC, e.g., the second peak value **124** in the MEM spectrum **120**, or the second peak value **134** in the MEM spectrum **130**.

[0102] In block **106 (FIG. 6)**, the pulse detection process **60***b* evaluates the energy values in the MEM spectrum to determine the frequency of the second peak in the MEM spectrum. For example, if the pulse detection process **60***b* evaluates MEM spectrum **120**, the frequency of the second peak **124** is determined. A similar analysis applied to the MEM spectrum **130** determines the frequency of the second peak **134**.

[0103] In block **108**, the frequency of the second peak **124** or **134** is compared with a predetermined threshold frequency to decide whether a heart sound is detected. For example, if the frequency of the second peak **124** or **134** is less than or equal to a threshold frequency, e.g., 100 Hz, the pulse detection process **60***b* determines that a heart sound was detected. Alternative embodiments of the invention may use values other than 100 Hz for the predetermined threshold frequency.

[0104] If a heart sound was detected, the pulse detection process **60***b* proceeds from decision block **110** to block **112** and determines that a pulse is present in the patient, thus advising against application of a defibrillation pulse. If, in decision block **110**, a heart sound was not detected, the pulse detection process **60***b* determines in block **114** that the patient is pulseless and that defibrillation may be appropriate for the patient. In that case, further signal processing of ECG data obtained from the patient is preferably performed to determine the applicability of defibrillation therapy, e.g., as described in U.S. Pat. No. 4,610,254, referenced earlier.

[0105] One example illustrating the processing performed by the pulse detection process **60***b* is shown in **FIGS. 8A and 8B**. **FIG. 8A** is a graph depicting a PCG waveform **140** of raw PCG data obtained from a patient in a manner as discussed above in regard to block **100 (FIG. 6)**. Although not shown in **FIG. 8**, the PCG waveform **140** may be filtered to reduce noise and other signal contaminants (e.g., as described earlier in reference to **FIG. 5B**).

[0106] For purposes of demonstrating the detection of heart sounds in the detection process **60***b*, an MEM spectrum of the data in the PCG waveform **140** is computed for a number of instances in time, and the frequency of the second peak of each MEM spectrum is identified, as shown by the circles in **FIG. 8**B, without regard to whether the selected instance of time corresponds with a heart sound candidate. Of course, in actual operation where results are needed for immediate and accurate evaluation of a patient, it is preferable that the PCG data first be screened for heart sound candidates.

[0107] In **FIG. 8**B, the circles enclosing an "x" identify the MEM spectra that, for this example, have a second peak located at or below a threshold frequency of 100 Hz. Note that, for the most part, the circles with an "x" in **FIG. 8B** correspond in time with the heart sounds evident in the PCG waveform **140** shown in **FIG. 8A**. For each circled "x," the pulse detection process **60***b* decides that a heart sound, and thus a pulse, is present in the patient.

[0108] **FIG. 9** illustrates another pulse detection process **60***c* that also uses an MEM spectrum as calculated in block **104** of the detection process **60***b*. Instead of analyzing the frequency location of the second peak in the MEM spectrum, as performed in the process **60***b*, the process **60***c* analyzes the energy value of the second peak in the MEM spectrum.

[0109] The detection process **60***c* begins at block **150** by obtaining PCG data from the patient in a manner as discussed earlier with respect to block **70 (FIG. 4)**. The PCG data is analyzed in block **152** to identify PCG data corresponding to the time when a heart sound **S1** or **S2** likely occurred. The analysis performed in block **152** may include an energy comparison process or ECG analysis as described earlier with respect to block **102** of pulse detection process **60***b* **(FIG. 6)**. An MEM spectrum of the heart sound candidate is then computed in block **154** in a manner as discussed earlier with respect to block **104 (FIG. 6)**. Also, as noted before, the energy spectrum calculation process may be run continuously.

[0110] In block **156**, the pulse detection process **60***c* evaluates the energy values in the MEM spectrum to locate the second peak value in the spectrum. The energy value of the second peak, determined in a block **158**, is used as a feature indicative of the presence of a heart sound, and is compared in block **160** with a predetermined threshold energy to decide whether a heart sound was detected. If the energy value of the second peak exceeds the threshold energy, the pulse detection process **60***c* determines in decision block **162** that a heart sound was detected.

[0111] If, in decision block **162**, a heart sound was detected, the pulse detection process **60***c* determines in block **164** that a cardiac pulse is present in the patient. In that circumstance, the detection process **60***c* may advise against providing defibrillation therapy to the patient. The detection process may also advise to check patient breathing. On the other hand, if a heart sound was not detected in decision block **162**, the pulse detection process **60***c* determines in block **166** that the patient is pulseless and advises that defibrillation therapy may be appropriate for the patient. In other embodiments, the detection process may advise the application of chest compressions or CPR in addition to or in place of advising defibrillation therapy for pulseless patients. An analysis of ECG data, as noted earlier, may be used to determine the applicability of defibrillation therapy.

[0112] **FIGS. 8A and 8C** illustrate one example of the processing performed by the pulse detection process **60***c*. As discussed earlier, **FIG. 8A** illustrates a PCG waveform **140** of raw PCG data obtained from a patient from which an MEM spectrum is computed for a number of instances in time. For each instance in time, the energy value of the second peak in the MEM spectrum is identified, as depicted by the circles in **FIG. 8C**.

[0113] In **FIG. 8**C, the circles enclosing an "x" are the MEM spectra with a second peak having an energy value above a selected threshold energy, e.g., 0 dB. While a threshold value of 0 dB is used in this specific example, other embodiments of the invention may use different threshold values to attain a desired sensitivity and specificity. The circles with an "x" in **FIG. 8C** generally correspond in time with the heart sounds evident in the PCG waveform **140** shown in **FIG. 8A**. Thus, for each circled "x," the pulse detection process **60***c* decides that a heart sound, and hence a cardiac pulse, is present in the patient.

[0114] On occasion, it is possible that noise in the PCG data may cause a false detection of a heart sound when using one of the detection processes **60***a*, **60***b*, or **60***c* described above. See, e.g., the two circled x's in **FIGS. 8B and 8C** immediately following the time reference of 0.6 seconds, which do not appear to correspond with heart sounds evident in **FIG. 8A**. If the signal-to-noise ratio of the PCG data obtained from the patient is not high enough to avoid such false detection of a heart sound, the detection processes **60***a*, **60***b*, and **60***c* of the pulse detection process may be combined in one or more ways to produce a pulse detection process with improved specificity. For example, **FIG. 10** illustrates a detection process **60***d* that combines features of the detection processes **60***a*, **60***b*, and **60***c*.

[0115] In **FIG. 10**, the pulse detection process **60***d* begins at block **170** by obtaining PCG data from a patient, e.g., in a manner as described earlier with respect to block **70** of pulse detection process **60***a* (**FIG. 4**). After the PCG data is obtained, estimates of the instantaneous energy and the background energy in the PCG data are computed in blocks **172** and **174**, e.g., in a manner as described earlier with respect to blocks **72** and **74**. The estimated instantaneous and background energy values are then compared in a block **176**, e.g., as described earlier with respect to block **76**, to produce a first detection statistic, or feature, indicative of the presence of a heart sound. The first detection statistic produced in block **176** is provided to a multidimensional classifier in block **186** that evaluates detection statistics to determine whether a heart sound was present. Of course, those having ordinary skill in the art will recognize that the instantaneous and background energies computed in blocks **172** and **174** may also be directly provided as separate detection statistics to a multidimensional classifier in block **186** for joint classification with any other detection statistics provided to the classifier (i.e., eliminating the comparison performed in block **176**).

[0116] The PCG data obtained in block **170** is also used in identifying a heart sound candidate and computing an MEM spectrum in block **178**, in a manner as described earlier with respect to blocks **102** and **104** of pulse detection process **60***b* (**FIG. 6**). Once the MEM spectrum is computed, the pulse detection process **60***d* determines in block **180** the location of the second peak in the MEM spectrum.

[0117] The frequency of the second peak is determined in a block **182** and provided as a second detection statistic, or feature, to the classifier in block **186**. Alternatively, the second detection statistic may be produced by comparing the frequency of the second peak with a threshold frequency, e.g., in a manner as described earlier with respect to block **108** (**FIG. 6**), to produce the second detection statistic.

[0118] In block **184**, the pulse detection process **60***d* also determines the energy value at the second peak and provides the energy value as a third detection statistic, or feature, to the classifier in block **186**. The second peak energy may alternatively be compared with a threshold energy, e.g., in a manner as described earlier with respect to block **160** (**FIG. 9**), to produce the third detection statistic.

[0119] The classifier in block **186** jointly classifies the first, second, and third detection statistics using a multidimensional classifier to determine whether a heart sound, and hence a pulse, is present in the patient. Techniques for constructing multidimensional classifiers are well-known in the art. For an expanded description of classifiers suitable for use in the present invention, see, e.g., R. Duda and P. Hart, Pattern Classification and Scene Analysis, published by John Wiley & Sons, New York, and incorporated herein by reference.

[0120] The classifier in block **186** may also use a voting scheme to determine whether a pulse is present in the patient. For example, if any of the first, second, or third detection statistics indicates the detection of a heart sound (i.e., the instantaneous energy exceeded the background energy by a threshold value, the frequency of the second peak was equal to or less than a threshold frequency, or the energy of the second peak exceeded a threshold energy), the classifier may determine that a pulse is present in the patient. Alternatively, the classifier in block **186** may determine that a pulse is present by finding that a combination of the first, second, and third detection statistics indicates the presence of a heart sound (e.g., a positive indication from the first detection statistic combined with a positive indication from the second or third detection statistics, etc.). The classifier in block **186** may also weight the first, second, or third detection statistics to emphasize one detection statistic over another in deciding whether a heart sound was detected.

[0121] If, in decision block **188**, a heart sound was detected, the pulse detection process **60***d* determines in block **190** that a pulse is present in the patient and may advise the operator of the defibrillator to not defibrillate the patient. The detection process may also advise to not perform CPR, in connection with or in place of any defibrillation advice. Otherwise, if a heart sound was not detected in decision block **188**, the pulse detection process **60***d* determines in block **192** that the patient is pulseless and that CPR/chest compressions and/or defibrillation therapy may be appropriate. An analysis of ECG data, as described earlier in reference to U.S. Pat. No. 4,610,254, may be used to determine if defibrillation therapy is appropriate.

[0122] An analysis of ECG data may also be combined with an analysis of PCG data to determine the presence of a cardiac pulse in the patient. In one aspect, detecting a QRS complex, or other ventricular complex, in the ECG data in time relation to the occurrence of a heart sound occurs may serve to confirm the detection of the heart sound. In another aspect, detecting a QRS complex or other ventricular com-

plex in the ECG data may be used to identify PCG data for use in the heart sound detection process, since a heart sound is expected to occur in time proximity to the occurrence of a ventricular complex if a cardiac pulse is present in the patient. This aspect of the invention is helpful in identifying a heart sound candidate in the PCG data. It is also helpful in identifying whether the patient is in a state of pulseless electrical activity. If a ventricular complex is found in the ECG data and a heart sound does not occur within an expected time period thereafter, the patient may be considered in a state of pulseless electrical activity (PEA) which may be reported to the operator of the device. The operator may also be prompted to deliver PEA-specific therapy, as discussed herein.

[0123] While the pulse detection processes described thus far use an analysis of PCG data to determine the presence of a cardiac pulse, the pulse detection processes may analyze other physiological signals sensed in the patient for features indicative of the presence of a cardiac pulse. For instance, variations in the patient's transthoracic impedance may be associated with the discharge of blood from the heart. By monitoring characteristic variations in the patient's transthoracic impedance, the pulse detection process may monitor the patient's cardiac output, and hence determine the presence of a cardiac pulse.

[0124] Another physiological signal for use with the present invention may be obtained from a piezoelectric sensor, e.g., piezo film, placed on the surface of the patent's body. Vibrations in the chest wall caused by the patient's heart cause the piezo film to produce corresponding electric signals. The pulse detection processes of the present invention may analyze the electric signals to determine whether a cardiac pulse is present. Additional detail regarding piezoelectric sensors and pulse detection processes that use piezoelectric signal data is provided in the copending U.S. Patent Application titled APPARATUS, SOFTWARE, AND METHODS FOR CARDIAC PULSE DETECTION USING A PIEZOELECTRIC SENSOR, filed concurrently herewith as application Ser. No. 10/229,321, and expressly incorporated by reference herein.

[0125] Another physiological signal that could be used in the present invention is obtained from one or more accelerometers placed on the patient. Vibrations in the patient from the patient's heart cause the accelerometer to output one or more electric signals, depending on the sensed axes of the accelerometers. These signals may be analyzed for one or more features indicative of a cardiac pulse. Additional detail regarding accelerometers and pulse detection processes using accelerometer signal data is provided in the copending U.S. Patent Application titled APPARATUS, SOFTWARE, AND METHODS FOR CARDIAC PULSE DETECTION USING ACCELEROMETER DATA, filed concurrently herewith as application Ser. No. 10/229,339, and expressly incorporated by reference herein.

[0126] Yet another physiological signal that could be used in the invention is derived from light-based techniques similar to photodetection (e.g., a pulse oximetry signal). Pulse oximetry uses light transmitted through the patient's skin to evaluate the oxygenation of the patient's blood. The presence of a cardiac pulse is reflected in the pulse oximetry signal. Apparatus and techniques for obtaining a pulse oximetry signal are well known in the art. One suitable system includes a sensor with a red LED, a near-infrared LED, and a photodetector diode. The sensor is configured to place the LEDs and photodetector diode directly on the skin of the patient, typically on a digit (finger or toe) or earlobe. Other places on the patient may also be suitable, including the forehead or the chest. The LEDs emit light at different wavelengths, which light is diffused through the vascular bed of the patient's skin and received by the photodetector diode. The resulting pulse oximetry signal may then be analyzed according to the present invention for one or more features indicative of a cardiac pulse. Other simpler versions of a light-based pulse detection system may be used, including a version with a single light source of one or more wavelengths. The absorption or reflectance of the light is modulated by the pulsatile arterial blood volume and detected using a photodetector device. One example is the Peripheral Pulse Sensor device marketed by Physio-Control in the 1970's. Light-based techniques for pulse detection are described in greater detail below.

[0127] A CO_2 waveform signal obtained from a standard capnography system is another physiological signal that could be used in the present invention. The CO_2 waveform is known to be affected by "cardiogenic oscillations" which are oscillations in the capnogram associated with the beating of the heart against the lungs. The capnogram may therefore be analyzed in the present invention to determine the presence of a cardiac pulse in the patient, particularly when the analysis identifies the presence of cardiac oscillations. See e.g., J. S. Gravenstein et al., Gas Monitoring in Clinical Practice, 2nd edition, Butterworth-Heinemann pp. 23-42 (1995), incorporated herein by reference.

[0128] Still another physiological signal that could be used in the present invention is a Doppler probe signal, preferably obtained from a standard continuous waveform (CW) Doppler system. A Doppler probe is attached to the patient and detects mechanical cardiac activity by sensing frequency shifts known as Doppler shifts. In accordance with the present invention, a CW Doppler probe detects Doppler shifts associated with cardiac movement and the morphology of the Doppler shifts is analyzed to determine if a pulse is present in the patient. See e.g., L. A. Geddes et al., Principles of Applied Biomedical Instrumentation, 3rd edition, John Wiley and Sons, Inc., pp. 184-209 (1989), incorporated herein by reference.

[0129] Although analysis of impedance signal data is discussed below as a way of describing further embodiments of the present invention, those of ordinary skill in the art will appreciate that the pulse detection processes of the present invention may use any physiological signal or combination of different physiological signals that reveal the presence of a cardiac pulse. These signals include, without limitation, piezoelectric signals, accelerometer signals, pulse oximetry signals, CO_2 waveform signals, and Doppler probe signals as indicated above, as well as PCG signals, ECG signals, and impedance signals.

[0130] **FIG. 11** illustrates a pulse detection process **200** that uses an analysis of impedance signal data to determine the presence of a pulse in a patient. Preferably, the impedance signal data selected for analysis is obtained during time intervals associated with ventricular complexes in the patient's ECG.

[0131] Beginning in block **202**, the pulse detection process **200** captures both ECG and impedance signal data, synchro-

nized in time, for a predetermined time interval (e.g., 10 seconds). Preferably, persons around the patient are advised to not touch the patient during this time interval (e.g., the device could report "Analyzing now . . . Stand clear"). Alternatively, the ECG and impedance capturing step may continue until the first or a specified number of ventricular complexes, such as QRS complexes, in the ECG have been identified, or in the event of asystole or a low heart rate, a predetermined maximum period of time (e.g., 10 seconds) has passed.

[0132] In block **204**, the pulse detection process **200** locates QRS complexes in the captured ECG signal. Identification of QRS complexes can be done using methods published in the literature and well-known to those skilled in the art of ECG signal processing. For example see, Watanabe K., et al., "Computer Analysis of the Exercise ECG: A Review," Prog. Cardiovasc Dis. 22: 423-446, 1980.

[0133] In block **206**, for each time that a QRS complex was identified in the ECG signal, a segment of filtered impedance signal data obtained from the captured impedance data is selected. In one embodiment of the invention, the time window of each segment of impedance data is approximately 600 milliseconds in length, and commences in time prior to the end of the identified QRS complex. If no QRS complexes were identified in the captured ECG signal in block **204** (as would happen for example, during asystole), no segments of impedance data are selected in block **206**.

[0134] In block **208**, one or more measurements are made on a segment of impedance signal data selected in block **204** to identify or calculate a feature indicative of a cardiac pulse. Non-limiting examples of the measurements may include one or more of the following temporal parameters:

[0135] (1) peak-to-peak amplitude of the impedance signal in the segment (measured in milliohms);

[0136] (2) peak-peak amplitude of the first derivative of the impedance signal in the segment (measured in milliohms per second);

[0137] (3) energy of the impedance signal in the segment (preferably calculated by squaring and summing each of the impedance data values in the segment); or

[0138] (4) a pattern matching statistic.

[0139] The previously described instantaneous/background energy methods, as well as the spectral methods described herein, could be used in block **208** as well to identify or calculate a feature indicative of a cardiac pulse.

[0140] As to pattern matching, the segment of impedance signal data is compared with one or more previously identified impedance signal patterns known to predict the presence of a pulse. The comparison produces a pattern match statistic. Generally, in this context, the greater the value of the pattern match statistic, the closer the patient's impedance signal matches a pattern impedance signal that predicts the presence of a pulse. Other candidate measurements will be apparent to those skilled in the art, and may be used instead of, or in addition to, the aforementioned measurements. A measurement resulting from the analysis in block **208** constitutes a feature of the impedance signal data that may be indicative of the presence of a pulse.

[0141] In decision block **210**, the one or more features from block **208** are evaluated to determine the presence of a cardiac pulse in the patient. The embodiment shown in **FIG. 11** compares the one or more features to predetermined thresholds to determine whether or not a pulse is detected. For example, an impedance peak-to-peak amplitude measurement would be consistent with the presence of a pulse if the measurement exceeded a certain threshold (e.g., 50 milliohms). Similarly, an impedance energy measurement would be consistent with a pulse if its magnitude exceeded a predetermined threshold. Likewise, a pattern matching statistic would be consistent with a pulse if it exceeded a predetermined threshold. If the feature exceeded the specified threshold, the pulse detection process determines that a pulse was detected, as indicated at block **212**. If the feature did not exceed the specified threshold, a pulse was not detected, as indicated at block **214**. If no segments of impedance signal data were selected in block **206** (i.e., no QRS complexes were located in block **202** in the captured ECG), the pulse detection process **200** would determine that a pulse was not detected, as indicated at block **214**.

[0142] The embodiment shown in **FIG. 11** uses thresholding in block **210** to determine whether a pulse was detected. However, those skilled in the art will recognize other forms of classification that may suitably be used in the invention. For example, multidimensional classifiers may be used in decision block **210** to determine whether a pulse was detected. Separate analyses of the amplitude and energy in the impedance data segment may be performed, with the resultant outcome of each analysis constituting a detection statistic that is provided to a multidimensional classifier. The detection statistics may be weighted and compared in the classifier to determine an overall conclusion whether a pulse is present in the patient. In other embodiments, individual calculations of instantaneous and background amplitudes and/or energies may be provided as detection features for evaluation in a multidimensional classifier. Pattern match statistics may also be evaluated in the multidimensional classifier, as may other candidate measurements of the impedance signal data. Furthermore, spectral techniques can be used, such as the peak frequency or energy techniques described previously. Techniques for constructing multidimensional classifiers are known in the art. See, e.g., R. Duda and P. Hart, Pattern Classification and Scene Analysis, referenced earlier and incorporated herein by reference.

[0143] After determining whether a pulse was detected (block **212**) or not detected (block **214**), the pulse detection process **200** determines whether all of the segments of impedance signal data selected in block **206** have been analyzed. If not, the analysis and decision process of blocks **208**, **210**, **212**, and **214** is preferably repeated for a new impedance data segment. This continues until all of the impedance data segments selected in block **206** have been analyzed.

[0144] It is recognized that the resulting determination (pulse detected or no pulse detected) may not be the same for each impedance data segment analyzed. An additional decision step is used to determine the overall outcome of the pulse detection process **200**. As indicated at decision block **218**, the pulse detection process **200** may evaluate the determinations for each impedance data segment and decide that a pulse is present in the patient if a pulse was detected in a simple majority of the impedance segments analyzed.

Of course, other voting schemes may be used. If, in decision block **218**, a majority is found, the pulse detection process concludes that a cardiac pulse is present in the patient, as indicated at block **220**. Otherwise, the pulse detection process **200** concludes that the patient is pulseless, as indicated at block **222**.

[**0145**] Requiring a pulse to be found in more than a simple majority of the impedance data segments would improve the specificity of the detection, but decrease the sensitivity for detecting a pulse. Conversely, requiring a pulse to be found for just one impedance segment or for less than a majority of the impedance segments would improve sensitivity for detecting a pulse but decrease specificity. If the pulse detection process **200** concludes that a pulse is present in the patient, the process **200** may optionally proceed to check the pulse rate of the patient, as illustrated in **FIG. 12**.

[**0146**] Turning to **FIG. 12**, in block **224**, the number of QRS complexes (located in block **204** in **FIG. 11**) are counted. Decision block **226** subsequently compares the number of QRS complexes to a threshold. In one exemplary embodiment, the threshold is 5, corresponding to a heart rate of approximately 30 bpm. If the number of QRS complexes is at least equal to the threshold, the pulse detection process **200** proceeds to block **228**, concluding that the patient has a pulse and an adequate pulse rate. If the number of QRS complexes is less than the threshold, the pulse detection process **200** proceeds to block **230**, concluding that the patient has a pulse, but also severe bradycardia. At very low heart rates, however, the blood flow may be insufficient to life. For that reason, below a certain heart rate (e.g., 30 bpm) the patient may instead be considered pulseless.

[**0147**] While the pulse detection process shown in **FIG. 11** includes capturing both ECG and impedance signal data, and selecting the segments of impedance signal data based on ventricular complexes located in the ECG, other pulse detection processes may not capture or use the ECG signal. In **FIG. 13**, an alternative pulse detection process **232** begins by capturing only impedance signal data from the patient, as indicated at block **234**. Depending on the length of the time interval in which impedance data is captured, it may be advantageous to select a segment of the impedance signal data for further analysis, as indicated at block **236**. In that regard, one suitable selection process includes scanning the impedance signal data for the maximum peak and selecting a segment of data that surrounds the detected maximum peak.

[**0148**] For exemplary purposes, the pulse detection process **232** is shown evaluating the selected segment of impedance signal data using a pattern match analysis. However, those skilled in the art will recognize that other techniques (e.g., analysis of the amplitude or energy—temporal or spectral—in the impedance signal data, as discussed above), may be used. In block **238**, the selected impedance data segment is compared with previously identified impedance signal patterns known to predict the presence of a pulse. The resulting pattern match statistic is evaluated against a threshold in decision block **240** to determine whether a pulse was detected in the patient. If the pattern match statistic exceeded the threshold, the pulse detection process **232** concludes in block **241** that a pulse was detected in the patient. Otherwise, the pulse detection process **232** concludes that the patient is pulseless, as indicated in block **242**. At this point, the pulse detection process is finished. Alternatively, if a pulse was detected in the patient, the pulse detection process **232** may proceed to evaluate the patient's pulse rate in a manner described in reference to **FIG. 12**.

[**0149**] The transthoracic impedance signal can contain fluctuations due to cardiac pulses, respiration, or patient motion. To assess whether a patient has a pulse, it is desirable to suppress fluctuations in the patient's impedance that are due to causes other than cardiac pulses. Fluctuations due to noncardiac causes may contain components at frequencies similar to those of impedance fluctuations due to cardiac pulses. Consequently, bandpass filtering may not always adequately suppress fluctuations due to noncardiac causes.

[**0150**] Signal averaging of the impedance signal can be used to suppress fluctuations that are due to noncardiac causes. Signal averaging makes advantageous use of the fact that impedance fluctuations due to cardiac pulses are generally synchronized to ventricular complexes in the ECG signal, whereas other impedance fluctuations are asynchronous to ventricular complexes. Pulse detection may be more accurately accomplished using an averaged impedance signal.

[**0151**] A preferred method for signal averaging of the impedance signal first stores the continuous ECG and transthoracic impedance signals, synchronized in time, for a predetermined time interval (e.g., ten seconds). The locations of the QRS complexes (if any) in the stored ECG signal are determined. Using true mathematical correlation (or an alternative correlation technique such as area of difference), the QRS complexes are classified into types, where all QRS complexes of the same type have high correlation with the first occurring QRS complex of that type. The dominant QRS type is selected as the type containing the most members, with a preference for the narrowest QRS type when a two or more types tie for most members. Using the first QRS of the dominant type as a reference complex, the second QRS complex of the same type is shifted in time until it is best aligned with the reference complex (i.e., it achieves a maximum correlation value). The corresponding impedance signal is also shifted in time to stay synchronized with the time-shifted QRS complex. When the second QRS complex is optimally aligned with the reference complex, the two QRS complexes are averaged together. Their corresponding impedance signals, over a time period from about the start of the QRS complex to about 600 milliseconds after the end of the QRS complex, are also averaged together. The averaged QRS complex is then used as a new reference complex and the process of averaging both the QRS complexes and the corresponding impedance data is repeated with the remaining QRS complexes of the dominant type.

[**0152**] Preferably, during the subsequent averaging of the QRS complexes and impedance segments, the new QRS complex and impedance segment carry a weight of one and the previous averaged QRS complex and impedance segment carry a weight equal to the number of QRS complexes that have been included in the averaged QRS complex. When all of the QRS complexes of the dominant type have been processed as described above, the averaged impedance segment is evaluated using one or more of the techniques

previously described (e.g., amplitude, energy, pattern matching) to determine whether the patient has a pulse.

[0153] Averaging of the signal data (be it PCG data, impedance data, etc., or combinations thereof) may also be accomplished without evaluating ECG data. For example, segments of impedance data may be analyzed and classified into types where segments of the same type have a high correlation. Impedance data of a dominant type, for example, may then be averaged and evaluated as previously described (using amplitude, energy, pattern matching, etc.) to determine whether the patient has a pulse.

[0154] During severe bradycardia, there will be few QRS complexes in a 10-second period and signal averaging of the transthoracic impedance signal will not be as effective as when the heart rate is higher. However, at very low heart rates, there is unlikely to be enough blood flow to support life. For that reason, below a certain heart rate (e.g., 30 bpm), the patient may be considered pulseless.

[0155] While the pulse detection processes described thus far separately use a PCG signal or impedance signal to determine the presence of a pulse, it is further within the scope of the present invention to combine multiple physiological signals into a pulse detection process. For example, the pulse detection process **244** depicted in **FIG. 14** illustrates an exemplary process in which PCG data and impedance signal data are used in combination to determine the presence of a pulse. In block **246**, the pulse detection process **244** captures impedance signal data from the patient, and in this example, captures ECG data as well. This capturing process may be performed in a manner similar to that described with respect to block **202** in **FIG. 11**. In block **248**, the pulse detection process **244** calculates one or more detection features or statistics. For example, the detection process **244** may undertake actions similar to that described with respect to blocks **204**, **206**, **208**, and **210** to produce an impedance-based detection statistic reflecting a preliminary determination whether a pulse has been detected.

[0156] At the same time as, or before or after, the impedance signal analysis in blocks **246** and **248**, the pulse detection process **244** also undertakes a PCG signal analysis. In that respect, in block **250**, the detection process **244** obtains phonocardiogram (PCG) data from the patient as described earlier in block **70** of **FIG. 4**. The PCG data is used to calculate one or more detection features or statistics in block **252**. For example, the detection process **244** may undertake actions as described above with regard to any or all of the pulse detection processes **60***a*, **60***b*, and/or **60***c*. As noted earlier, **FIG. 10** illustrates a PCG-based detection process **60***d* that combines the detection processes **60***a*, **60***b*, and **60***c*. As shown in **FIG. 10**, each of the pulse detection processes produces a first, second, and third detection statistic that are fed to a multidimensional classifier. In regard to **FIG. 14**, the detection statistics from the impedance-based and PCG-based detection processes are provided to a classifier for evaluation, as shown in block **254**. The classifier in block **254** may be a multidimensional classifier as described above with respect to block **186** (**FIG. 10**). As noted earlier, the reference Pattern Classification and Scene Analysis by R. Duda and P. Hart, describes techniques for constructing suitable multidimensional classifiers. Additionally, techniques for multidimensional classifiers are discussed in U.S. Pat. No. 6,171,256, assigned to the assignee of the present invention and incorporated by reference herein.

[0157] The outcome of the classification performed in block **254** is provided to a decision block **256**. If the detection statistics are classified as indicating the presence of a pulse, the pulse detection process **244** determines in block **257** that a cardiac pulse is present and preferably advises against providing defibrillation therapy to the patient. On the other hand, if the detection statistics are classified as not indicating the presence of a pulse, the pulse detection process **244** determines in block **258** that a cardiac pulse was not detected and may advise the delivery of defibrillation therapy.

[0158] There is no restriction as to what constitutes a detection feature/statistic for the purposes of the pulse detection process **244**. A detection feature/statistic may suitably be a preliminary determination of whether a pulse is present (i.e., a binary "yes" or "no" outcome). A detection feature/statistic may also be data produced from the analyzed physiological signal. For example, a detection feature/statistic may be an amplitude, energy, or pattern match statistic as discussed earlier. The detection feature/statistic may also be an energy or frequency value in the temporal or spectral domain. A combination of two or more analyzed physiological signals may advantageously provide a more robust pulse detection process with improved detection characteristics.

[0159] A pulse detection process as described herein may be used as part of an overall shock advisory process in a defibrillator. The shock advisory process determines whether to recommend defibrillation or other forms of therapy for a patient. **FIG. 15** illustrates a pulse detection/defibrillation process **260**, preferably for use in an automated external defibrillator (AED) capable of providing a defibrillation pulse if a patient is determined to be pulseless and in ventricular fibrillation or ventricular tachycardia. The AED may also be configured to prompt the application of chest compressions or CPR as appropriate.

[0160] In the pulse detection/defibrillation process **260**, an AED initializes its circuits when it is first turned on, as indicated at block **262**. The defibrillation electrodes of the AED are placed on the patient. When the AED is ready for operation, the process **260** performs an analysis of the patient, as indicated at block **264**, in which the AED obtains selected parameters such as impedance signal data, ECG data, and/or PCG data, from the patient. During the analysis performed in block **264**, the AED preferably reports "Analyzing now . . . Stand clear" to the operator of the AED.

[0161] Using the information obtained in the patient analysis, the process **260** determines in decision block **266** whether the patient is experiencing ventricular fibrillation (VF). If VF is present in the patient, the process **260** proceeds to block **276** where the AED prepares to deliver a defibrillation pulse to the patient. In that regard, an energy storage device within the AED, such as a capacitor, is charged. At the same time, the AED reports "Shock advised" to the operator of the AED.

[0162] Once the energy storage device is charged, the process **260** proceeds to block **278** where the AED is ready to deliver the defibrillation pulse. The operator of the AED

is advised "Stand clear . . . Push to shock." When the operator of the AED initiates delivery of the defibrillation pulse, the process **260** delivers the defibrillation shock to the patient, as indicated in block **280**.

[**0163**] The AED preferably records in memory that it delivered a defibrillation pulse to the patient. If the present pulse delivery is the first or second defibrillation shock delivered to the patient, the process **260** may return to block **264** where the patient undergoes another analysis. On the other hand, if the pulse delivery was the third defibrillation pulse to be delivered to the patient, the process **260** may proceed to block **274** where the AED advises the operator to commence providing CPR therapy to the patient, e.g., by using the message "Start CPR." The "No shock advised" prompt shown in block **274** is suppressed in this instance. The AED may continue to prompt for CPR for a predetermined time period, after which the patient may again be analyzed, as indicated in block **264**.

[**0164**] Returning to decision block **266**, if VF is not detected in the patient, the process **260** proceeds to decision block **268** and determines whether a cardiac pulse is present in the patient. The pulse detection performed in block **268** may be any one or a combination of the pulse detection processes described above.

[**0165**] Breathing may be checked manually by the operator or automatically by the device, as discussed below in regard to block **374** of **FIG. 17**. If, at decision block **268**, a pulse is detected in the patient and the patient is not breathing, the process **260** proceeds to block **270** and reports "Pulse detected . . . Start rescue breathing" to the operator. The process **260** may also report "Return of spontaneous circulation" if a pulse is detected in the patient any time after the delivery of a defibrillation pulse in block **280**. In any event, after a predetermined time period for rescue breathing has completed, the process **260** preferably returns to block **264** to repeat an analysis of the patient.

[**0166**] If a cardiac pulse is not detected at decision block **268**, the process **260** determines whether the patient is experiencing ventricular tachycardia (VT) with a heart rate of greater than a certain threshold, e.g., 100 beats per minute (bpm), as indicated at decision block **272**. Other thresholds such as 120, 150, or 180 bpm, for example, may be used. If the determination at decision block **272** is negative, the process **260** proceeds to block **274** and advises the operator to provide CPR therapy. Again, at this point, the AED reports "No shock advised . . . Start CPR" to the operator. The prompt to provide CPR is preferably provided for a defined period of time. When the period of time for CPR is finished, the process **260** preferably returns to block **264** and performs another analysis of the patient. If the determination at decision block **272** is positive (i.e., the patient is experiencing VT with a heart rate greater than the threshold), the process **260** performs the shock sequence shown at blocks **276**, **278**, **280** to deliver a defibrillation pulse.

[**0167**] Those having ordinary skill in defibrillation and cardiac therapy will recognize variations and additions to the process **260** within the scope of the invention. **FIG. 16**, for example, illustrates an alternative pulse detection/defibrillation process **300** for use in an AED. As with the process **260** in **FIG. 15**, the AED begins by initializing its circuits at block **302**. At block **304**, the AED performs an analysis of the patient in a manner similar to that described with respect to block **264** in **FIG. 15**. After completing the analysis of the patient, the process **300** proceeds to decision block **306** to determine whether a pulse is present in the patient. The pulse detection performed in block **306** may be, for example, any one of the pulse detection processes discussed above or a combination or variation thereof.

[**0168**] If a pulse is detected in the patient, the process **300** may enter a monitoring mode at block **308** in which the patient's pulse is monitored. The pulse monitoring performed at block **308** may use any one or a combination of the pulse detection processes described above. Preferably, the process **300** is configured to proceed from block **308** to block **304** after expiration of the predetermined monitoring time period. If the pulse monitoring at block **308** determines at any time that a pulse is no longer detected, the process **300** returns to block **304** to perform another analysis of the patient. The process **300** also preferably reports the change in patient condition to the operator.

[**0169**] If, at decision block **306**, a pulse is not detected in the patient, the process **300** proceeds to decision block **310** where it determines whether the patient has a shockable cardiac rhythm (e.g., VF or VT). As referenced earlier, U.S. Pat. No. 4,610,254, incorporated herein by reference, describes a suitable method for differentiating shockable from non-shockable cardiac rhythms.

[**0170**] If a shockable cardiac rhythm, such as VF or VT, is detected, the process **300** proceeds to a shock delivery sequence at blocks **312**, **314**, and **316**, which may operate in a manner similar to that described with respect to blocks **276**, **278**, and **280** in **FIG. 15**. If the pulse delivery was the third defibrillation shock delivered to the patient, the process **300** may proceed to block **318** and prompt the delivery of CPR, as discussed with block **274** in **FIG. 15**.

[**0171**] If VF or VT is not detected at decision block **310**, the process **300** checks for asystole, as indicated at block **320**. One suitable process for detecting asystole is described in U.S. Pat. No. 6,304,773, assigned to the assignee of the present invention and incorporated herein by reference. If asystole is detected at block **320**, the process **300** proceeds to prompt the delivery of CPR, as indicated at block **318**. If asystole is not detected, the process **300** determines that the patient is experiencing pulseless electrical activity (PEA), as indicated at block **322**. PEA is generally defined by the presence of QRS complexes in a patient and the lack of a -detectable pulse, combined with no detection of VT or VF. Detection of PEA in block **322** is achieved by ruling out the presence of a pulse (block **306**), detecting no VF or VT (block **310**), and detecting no asystole (block **320**). Alternatively, if the ECG signal is monitored for QRS complexes (e.g., as shown at block **202** in **FIG. 11**), the process **300** may conclude the patient is in a state of PEA if it repeatedly observes QRS complexes without detection of a cardiac pulse associated therewith. If a PEA condition is detected, the process **300** proceeds to block **324** and prompts the operator to deliver PEA-specific therapy to the patient. One suitable method of treating PEA is described in U.S. Pat. No. 6,298,267, incorporated by reference herein. The process **300** may prompt other therapies as well, provided they are designed for a PEA condition. After a PEA-specific therapy has been delivered to the patient, possibly for a predetermined period of time, the process **300** returns to block **304** to repeat the analysis of the patient.

[0172] **FIG. 17** illustrates yet another pulse detection/defibrillation process **350** that may be used in an AED. At block **352**, after the AED has been turned on, the AED initializes its circuits. The defibrillation electrodes are also placed on the patient. The AED is then ready to analyze the patient, as indicated at block **354**. This analysis may be performed in a manner similar to that described with respect to block **264** in **FIG. 15**.

[0173] If at any point the AED determines that the defibrillation electrodes are not connected to the AED, the process **350** jumps to block **356** where the AED instructs the operator to "Connect electrodes." When the AED senses that the electrodes are connected, the process **350** returns to the analysis in block **354**. Likewise, if the AED finds itself in any other state where the electrodes are not connected, as represented by block **358**, the process **350** jumps to block **356** where it instructs the operator to connect the electrodes.

[0174] Furthermore, during the analysis performed in block **354**, if the AED detects motion on the part of the patient, the process **350** proceeds to block **360** where the AED reports to the operator of the AED "Motion detected . . . Stop motion." If the patient is moved during the analysis process **354**, the data obtained during the analysis is more likely to be affected by noise and other signal contaminants. Motion of the patient may be detected in the impedance signal data collected by the present invention. A suitable method for detecting motion of the patient is described in U.S. Pat. No. 4,610,254, referenced earlier and incorporated by reference herein. The AED evaluates the impedance measured between the defibrillation electrodes placed on the patient. As noted earlier, noise and signal components resulting from patient motion cause fluctuations in the impedance signal, generally in a frequency range of 1-3 Hz. If the measured impedance fluctuates outside of a predetermined range, the AED determines that the patient is moving or being moved and directs the process **350** to proceed to block **360**. When the motion ceases, the process **350** returns to the analysis in block **354**.

[0175] The process **350** next proceeds to decision block **362** where it determines whether a pulse is detected in the patient. Again, the pulse detection processes performed in decision block **362** may be, for example, one of the pulse detection processes described above or combination or variation thereof.

[0176] If a pulse is not detected in the patient, the process **350** proceeds to decision block **364** where it determines whether the patient has a shockable cardiac rhythm (e.g., VF or VT) or a non-shockable cardiac rhythm (such as asystole and bradycardia). As referenced earlier, one suitable method for differentiating shockable from non-shockable cardiac rhythms is disclosed in U.S. Pat. No. 4,610,254, incorporated herein by reference. If the patient's cardiac rhythm is determined to be shockable (e.g., VF or VT is found), the process **350** proceeds to blocks **366**, **368**, and **370** to deliver a shock to the patient. The shock delivery may be performed as described earlier with respect to blocks **276**, **278**, **280** in **FIG. 15**.

[0177] If the pulse delivery was the third defibrillation pulse to be delivered to the patient, the process **350** proceeds to block **372** where the AED advises the operator to commence providing CPR therapy to the patient. The CPR prompt may continue for a defined period of time, at which the process **350** returns to block **354** and performs another analysis of the patient.

[0178] If, at decision block **364**, the patient's cardiac rhythm is determined not shockable, the process **350** preferably proceeds to block **372** and advises the operator to provide CPR therapy, as discussed above.

[0179] Returning to decision block **362**, if a pulse is detected in the patient, the process **350** proceeds to decision block **374** where it determines whether the patient is breathing. In that regard, the AED may again use the impedance signal for determining whether a patient is breathing. As noted earlier, fluctuations in impedance of the patient below **1** Hz are largely indicative of a change in volume of the patient's lungs. The breathing detection at block **374** (and at blocks **376** and **378**, discussed below) may monitor the impedance signal for characteristic changes that indicate patient breathing, e.g., as described in Hoffmans et al., "Respiratory Monitoring With a New Impedance Plethysmograph," Anesthesia 41: 1139-42, 1986, and incorporated by reference herein. Detection of breathing may employ a process similar to that described above for detection of a pulse (i.e., evaluating impedance amplitude, energy, or pattern), though a different bandpass filter would be used to isolate the frequency components that more closely demonstrate patient breathing. If automatic means for detecting breathing in the patient are not available, the AED may ask the operator of the AED to input information (e.g., by pressing a button) to indicate whether the patient is breathing.

[0180] If, at decision block **374**, the process **350** determines that the patient is not breathing, the process **350** proceeds to a block **376** where the operator of the AED is advised to commence rescue breathing. In that regard, the AED reports to the operator "Pulse detected . . . Start rescue breathing." The AED also continues to monitor the patient's cardiac pulse and returns to block **354** if a cardiac pulse is no longer detected. If, at any point during the provision of rescue breathing, the AED detects that the patient is breathing on his own, the process **350** proceeds to block **378** where the AED monitors the patient for a continued presence of breathing and a cardiac pulse.

[0181] Returning to decision block **374**, if the process **350** determines that the patient is breathing, the process **350** proceeds to block **378** where the AED monitors the pulse and breathing of the patient. In that regard, the AED reports "Pulse and breathing detected . . . Monitoring patient." If, at any time during the monitoring of the patient the process **350** determines that the patient is not breathing, the process **350** proceeds to block **376** where the operator of the AED is advised to commence rescue breathing. If a cardiac pulse is no longer detected in the patient, the process **350** proceeds from either block **376** or **378** to block **354** to commence a new analysis of the patient.

[0182] Lastly, as noted in **FIG. 17**, during the rescue breathing procedure in block **376** or the monitoring procedure performed in block **378**, the AED may assess whether CPR is being administered to the patient. If the AED finds that CPR is being performed, the AED may prompt the operator to cease providing CPR. If, during the CPR period of block **372**, the AED determines that CPR is not being administered to the patient, the AED may remind the opera-

tor to provide CPR therapy to the patient. One method for determining whether CPR is being administered is to monitor patient impedance to observe patterns of impedance fluctuation in the patient that are indicative of CPR. During CPR, repetitive chest compression typically causes repetitive fluctuations in the impedance signal.

[0183] **FIG. 18** illustrates yet another application in which pulse detection according to the present invention may be used. The application described in **FIG. 18** pertains to auto-capture detection in cardiac pacing.

[0184] Specifically, the auto-capture detection process **380** begins at block **382** in which pacing therapy for the patient is initiated. A counter N, described below, is set to equal 0. At block **384**, a pacing pulse is delivered to the patient. Thereafter, physiological signal data is obtained from the patient, as indicated at block **386**. This data may include, for example, PCG data, ECG data impedance signal data, piezoelectric signal data, accelerometer data, etc., or a combination of this data, that is capable of indicating the presence of a cardiac pulse. The patient's physiological signal data is used in block **388** to detect the presence of a cardiac pulse. The pulse detection process used in block **388** may be, for example, any one or combination or variation of the pulse detection processes discussed above.

[0185] The sequence of delivering a pacing pulse and determining the presence of a cardiac pulse in blocks **384**, **386**, **388** may be repeated a number of times. With respect to **FIG. 18**, for example, the sequence is repeated five times. At block **390**, the counter N is evaluated, and if not yet equal to 5, the counter is incremented by 1 (block **392**), following which the process **380** returns to deliver another pacing pulse to the patient (block **384**).

[0186] If, at decision block **390**, the counter N equals 5, the process **380** determines at decision block **394** whether a cardiac pulse occurred consistently after each pacing pulse. The process **380** requires that some portion or all of the pacing pulses result in a detectable cardiac pulse before pronouncing that capture has been achieved. If the presence of a cardiac pulse is determined to consistently follow the pacing pulses, the process **380** determines that capture has been achieved, as in indicated at block **396**. Otherwise, the current of the pacing pulses is increased by a predetermined amount, e.g., 10 milliamperes, as indicated at block **398**. At block **399**, the counter N is set back to equal 0 and the process **380** returns to the pacing capture detection sequence beginning at block **384**. In this manner, the pacing current is increased until capture has been achieved.

[0187] In **FIG. 18**, the presence of a pulse is used to determine whether the pacing stimulus has been captured by the ventricles of the patient's heart. Detection of QRS complexes in the patient's ECG may also be used as patient physiological signal data to identify pacing capture. A QRS complex will occur immediately following the pacing stimulus if capture has been achieved. If QRS complexes are not observed, the current of the pacing pulses may be increased, as discussed above, until, capture has been achieved.

[0188] **FIG. 19** illustrates still another application in which pulse detection according to the present invention may be used. The process **400** described in **FIG. 19** is particularly suited for use in a manual defibrillator or patient monitor. Beginning at block **402**, the process **400** monitors the patient's ECG for QRS complexes. At block **404**, the process **400** also obtains other physiological signal data, such as PCG data, impedance signal data, piezoelectric signal data, accelerometer data, etc., from the patient. The process **400** uses the ECG and other physiological signal data in decision block **406** to determine the presence of a cardiac pulse. The pulse detection implemented in block **406** may be one of the pulse detection processes discussed herein.

[0189] If a pulse is detected, the process **400** determines whether a defibrillation pulse has been provided to the patient and if so, reports the return of spontaneous circulation to the operator, as indicated at block **418**. The process **400** then returns to block **402** to repeat the pulse detection analysis. If a pulse is not detected, the process **400** evaluates the ECG signal to determine whether the patient is experiencing ventricular fibrillation or ventricular tachycardia with a heart rate greater than 100 bpm. If so, then the process identifies the patient's condition and produces a VT/VF alarm, as indicated at block **410**. If not, the process **400** then proceeds to block **412** to check for an asystole condition.

[0190] Detection of asystole may be accomplished as noted earlier and described in greater detail in U.S. Pat. No. 6,304,773, incorporated herein by reference. If asystole is detected, the process **400** identifies the patient's condition and sounds an asystole alarm, as indicated at block **414**. Otherwise, the patient is experiencing PEA and the patient's condition is so identified, with the sound of a PEA alarm, as indicated at block **416**. In this manner, the operator of the manual defibrillator or monitor is kept advised of the patient's condition.

[0191] One having ordinary skill in the art will readily recognize that the present invention may be implemented by one or more devices that include logic circuitry. The one or more devices perform functions and/or methods as described above. The logic circuitry may include a processor, such as the processing circuit **38**, that may be programmable for a general purpose, or dedicated, such as a microcontroller, a microprocessor, a digital signal processor (DSP), etc. For example, a device implementing the invention may be a digital computer-like device, such as a general purpose computer selectively activated or reconfigured by a computer program stored in the computer. Alternatively, the device may be implemented as an application specific integrated circuit (ASIC), etc.

[0192] As described herein, a physiological signal that can be used for pulse detection, in accordance with the invention, may be derived from light-based techniques similar to photo detection, e.g., using a pulse oximetry signal. Pulse oximetry uses light transmitted through the patient's skin to evaluate the oxygenation level of the patient's blood. The presence of a a cardiac pulse is reflected in the pulse oximetry signal. Various apparatus and techniques for obtaining a pulse oximetry signal are well known in the art. However, described herein are a new apparatus and techniques for the derivation and use of physiological parameters obtained from a pulse oximetry signal, as well as apparatus and techniques for cardiac pulse detection based on the physiological parameters. In particular, cardiac pulse detection can be performed optically by processing a light detection signal over a period of time to detect a trend in pulsatile changes in blood volume.

[0193] One suitable optical system for cardiac pulse detection includes a sensor with a red LED, a near-infrared LED, and a photodetector diode. The sensor is configured to place the LEDs and photodetector diode directly on the skin of the patient, typically on a digit (finger or toe) or earlobe. Other places on the patient may also be suitable, including the forehead or the chest. The LEDs emit light at different wavelengths. The light emitted by the LEDs is diffused through the vascular bed of the patient's skin and received by the photodetector diode. The resulting pulse oximetry signal may then be analyzed according to the present invention to ascertain one or more physiological signals indicative of a cardiac pulse. In particular, detection of the transmitted light over a period of time may be used to ascertain trending of pulsatile changes in blood volume.

[0194] Other simpler versions of a light-based pulse detection system may be used, including a version with a single light source producing one or more wavelengths. The absorption or reflectance of the light is modulated by the pulsatile arterial blood volume and detected using a photodetector device. One example is the Peripheral Pulse Sensor device marketed by Physio-Control Manufacturing Co. in the 1970's.

[0195] Hence, in some embodiments, a system in accordance with the invention may provide an optical pulse detection system that includes, or is incorporated within, a defibrillator or other medical device. The defibrillator is capable of permitting selective defibrillation of a patient, if it is so indicated. In addition, the defibrillator or other medical device may be configured to provide information to the user concerning treatment of the patient based on the trend in pulsatile changes blood volume, or provide the treatment itself. For example, the defibrillator may permit selective defibrillation in response to light detection signals, and one or more associated physiological parameters indicated by the light detection signals, such as trending of pulsatile changes in blood volume. The defibrillator can be manual, automatic, semi-automatic, or the like. The defibrillator or other medical device may further include one or more light sources. The light sources transmit light into the patient, and are preferably placed onto the body of the patient, e.g., on a finger, toe, earlobe nose, lip, forehead, neck, or on the chest, including adjacent to the perimeter of a defibrillation electrode.

[0196] A medical device in accordance with the invention further includes a light detector. The light detector receives light that has been transmitted into the patient, and either pass-through transmitted through an appendage, e.g., transmission through a finger, toe, earlobe nose, or lip, or back-scatter reflected to produce reflected light from a surface such as the forehead, neck, chest, or the like. In other words, the light detector captures either transmitted or reflected light.

[0197] The light detector may by placed on the patient's body facing the light source for a transmissive detection or adjacent to the light source for a reflective detection. Multiple light sources and multiple detectors can be utilized to assist in distinguishing peripheral blood flow from true cerebral blood flow.

[0198] The light detector generates a light detection signal in response to the reflected or transmitted light. The combined light source and light detector are intended for detecting the presence of a pulse of the patient. They may be advantageously provided in a single device, which is also known as a pulse detector. Furthermore, the pulse detector, or either the light source and/or the light detector, can be provided either integrally with the defibrillator and the defibrillation electrodes, or together as a pulse detector separate from the defibrillation electrode that may provide a signal to the defibrillator or be used as part of a separate device.

[0199] The invention further contemplates a processor for processing the light detection signal to detect at least one physiological parameter. That physiological parameter can be the trending of pulsatile changes in blood volume in the vicinity of the light detector. In each case, the light detection signal level and waveform characteristics provides a correlation with the level and waveform characteristics of the physiological parameters. The processor may be adapted to repeat processing, and thereby further determine a trending statistic for any of the foregoing physiological parameters. In each case, the physiological parameter or trending statistic provides an indication of the presence of a cardiac pulse, and thus supports cardiac pulse detection.

[0200] Optionally, a medical device in accordance with the invention further may include a temperature sensor that generates a temperature signal. Then, the light detection signal is advantageously analyzed based on the temperature signal. A standard temperature sensor such as a thermistor or solid state device like a diode may be used to determine the ambient or skin temperature. The temperature of the tissue can also be determined by monitoring the characteristic change of the optical detector. The sensor has a characteristic signature versus temperature that could be utilized to monitor skin temperature.

[0201] Changes in the absorption coefficient and the scattering coefficient of the tissue/blood as a function of temperature can then be compensated in the processing of the transmitted or reflected light signal to produce a more reliable representation of a desired physiological parameter. This temperature sensor can also be used to compensate for changes in source emission as a function of temperature. This information can be used to adjust thresholds levels for the change in amplitude of the light detection signal that would be detected as a pulse.

[0202] In one set of embodiments, a defibrillator in accordance with the invention includes at least one defibrillation electrode to be applied to the patient. In addition, an optical pulse detector for detecting a pulse of the patient is attached to the defibrillation electrode.

[0203] Attachment of the optical pulse detector to the defibrillation electrode may be permanent or temporary. For example, the optical pulse detector may be attached to the defibrillation electrode by an adhesive tape, hook-and-loop fasteners, snap fit, friction fit, tear-away joint, or the like, or the pulse detector may be integrally built into the components of the defibrillation electrode. Preferably, attachment is such that the pulse detector can be readily detached from the defibrillation electrode, and attached to different positions on the patient, e.g., chest, neck and forehead. As an alternative, non-optical pulse detectors, such as electrical or acoustic pulse detectors, may be integrated with a defibrillator electrode, or made detachable from a defibrillator electrode, as described above. In each case, an integrated or

detachable pulse detector may provide efficiency and convenience to the user in placing the detector on the patient. Thus, as described herein, although the pulse detector preferably is optical, some embodiments may provide as detachable sensors other types of sensors, inlcuding mechanical sensors such as vibration/pressure wave sensors made with a piezoelectric material, or an acoustic microphone, may be made detachable from a defibrillation electrode.

[0204] In additional embodiments, the pulse detector may be applied in a single step with the defibrillation electrodes in a first location, e.g., the chest or abdomen, subsequently detached from the electrodes, and then reapplied to the patient in a second location on the patient's body, e.g., the neck or forehead. This enables the user to apply the electrodes and the optical or non-optical pulse detector in a single step, allowing the system to quickly assess the condition of the patient. If the quality of the pulse detection signal at the first location is not as desired, then the pulse detector can be detached from the electrode and reapplied in a second location such as the neck or forehead.

[0205] In another embodiment, a medical device may include a pulse detector with a light source that operates at two or more wavelengths of light. More specifically, the light source includes one or more light sources capable of transmitting light into the patient at least two wavelengths. Exemplary wavelengths for transmission of light into the patient are 549.5, 569, 760, 805, and 850 nm.

[0206] The light source may be implemented by a single source, operating at least two wavelengths, or by two or more sources, each operating at a different wavelength. Suitable light sources include LEDs, laser sources such as diode lasers or wavelength-tunable lasers, a polychromatic light source with a prism for separating wavelengths, or the like.

[0207] In addition, the medical device includes at least one light detector for receiving light that has been transmitted into the patient. Either a single photodetector can be used to detect both wavelengths, or different detectors can be used for the different wavelengths. The one or more light detectors generate light detection signals in response to light received at the different wavelengths that have been transmitted into the patient.

[0208] In these embodiments, a processor processes the light detection signals to ascertain at least one physiological parameter of the patient. Acquisition of light detection signals at two different wavelengths aids the processor in distinguishing artifacts from signals actually indicative of physiological parameters. The processor preferably is adapted to repeat processing after a number of times, to further determine trending statistics for a given physiological parameter such as pulsatile changes in blood volume.

[0209] As mentioned above, the processor may be adapted to further distinguish, from the light detection signals, an artifact from a signal of the patient corresponding to the physiological parameter. The artifact may be environmentally caused or patient dependent. The physiological signal may be one that corresponds to changes in blood volume caused by pulsatile blood flow.

[0210] In other embodiments, a medical device includes means for transmitting light into the patient, where the light has at least two or more different intensity levels. For example, two distinct light sources operating at different intensities may be provided. Light sources can be of the same wavelength or different, as described above. Also, the light sources can be implemented by any of the devices described above. In additional embodiments, a light source includes a single light source adjustable to emit light at distinct intensity levels.

[0211] In each case, a light detector is further included for receiving light that has been transmitted into the patient. The light detector can be a single photodetector, and sense the different intensities. Further, the light source may be integrated with the light source or sources, as a single pulse detection device. The light detector generates a light detection signal in response to the light that is received after it has been transmitted into the patient. In this case, the processor determines pulse parameters, and optionally also an artifact from the light detection signals.

[0212] As a further embodiment, a circuit or a processor within the medical device extracts a dc component of the light detection signal. In those cases, the intensity level of the light source may be adjusted according to the extracted dc component, or a gain of the light detector may be adjusted according to the extracted dc component, or both. Additionally, the intensity of the light source may be varied as a function of temperature.

[0213] **FIG. 20** is a block diagram of a defibrillator **419**A incorporating an optical, i.e., light-based, cardiac pulse detector with a multi-wavelength light source. As shown in **FIG. 20**, defibrillator **420** includes defibrillation electrodes **420**A, **420**B. In addition, defibrillator **419** includes a light detection module **422** with a first light source **421**, a second light source **423** and a light detector **425**. A processor **424** executes instructions stored in memory **426** to control a light detection interface **428** and defibrillation interface **430**, and process signals received via light detection interface **428**.

[0214] Light detection interface **428** includes circuitry to drive light sources **421**, **423** to generate light at different wavelengths. In particular, light sources **421**, **423** generate light at different wavelengths selected to provide different tissue and blood absorption characteristics. Light detector **425** receives the light transmitted into the patient by light sources **421**, **423** and generates light detection signals. For example, the light at different wavelengths may be transmitted and detected at different times. Hence, light detection interface **428** may selectively drive light sources **421**, **423**.

[0215] Light detection interface **428** receives the light detection signals from light detector **425** and passes the signals to processor **424**. Processor **424** processes the light detection signals to ascertain a physiological parameter that correlates with characteristics of the light detection signals. Again, the physiological parameter may be a trending of pulsatile changes in blood volume. The light detection signal may be correlated with a pulsatile change in blood volume for pulse detection. In particular, the light detection signal can be processed to correlate one of the amplitude and shape of the detection signal with the strength of the patient's pulse. The light detection signal can be monitored over a period of time and analyzed for any changes in amplitude, and shape over time. This could be used to assess the condition of a patient who may have a 'weak' pulse. This may be useful, for example, for a trauma patient. The pulse signal may be of sufficient amplitude to indicate a pulse is

detected, but over a period of time the patient's pulse may become weaker, which may signify that the patient's condition is deteriorating. Processor **424** could provide a message to alert the care provider to the change in the patient's condition. The analysis of the pulse signal for trends such as this may enable the care provider to give earlier treatment to improve the condition of the patient.

[**0216**] Using multiple wavelengths improves the ability of the sensor to distinguish differences in optical transmission due to environmental artifact and differences due to the biological parameter of interest. Changes in optical transmission due to environmental changes will be similar at multiple wavelengths. However, by properly selecting the wavelengths, one wavelength will have greater changes in optical transmission due to the biological parameter of interest than other wavelengths. This information can be processed to improve detection of changes due to the physiological parameter of interest. For example, processor **424** processes the light detection signal to ascertain a physiological parameter such as pulsatile changes in blood volume, or other physiological parameters useful in cardiac pulse detection. In some embodiments, processor **424** may process the light detection signal over a period of time to detect a trend in pulsatile changes in the flow of blood.

[**0217**] Processor **424** evaluates the physiological parameter to determine whether the parameter indicates the presence or absence of a cardiac pulse in the patient. Based on the indication of the presence or absence of a cardiac pulse, processor **42** determines whether defibrillation is appropriate. In particular, processor **42** permits selective defibrillation of the patient if the presence of a cardiac pulse is not indicated. In this case, the defibrillation may be automated, semi-automated or manual. Hence, processor **42** may control defibrillation interface **430** to deliver a defibrillation shock, or present to a user an indication that defibrillation shock should be delivered, i.e., as visual and/or audible instructions via a user interface such as a display screen or speaker. Alternatively, or in addition, processor **42** may provide instructions for delivery of CPR. Defibrillation interface **430** may include appropriate charging, storage and switching hardware for delivery of defibrillation shocks via defibrillation electrodes **420**A, **420**B.

[**0218**] **FIG. 21** is a block diagram of another defibrillator **419**B incorporating an optical pulse detector. Defibrillator **419**B conforms substantially to defibrillator **419**A of **FIG. 20**, but incorporates a light detector module **432** having a single light source **427**, rather than two light sources. Single light source **427** may transmit light at a single wavelength, or may be configured to selectively transmit light at multiple wavelengths. In each case, light detector **425** receives the transmitted light and generates one or more light detection signals for evaluation by processor **424**.

[**0219**] **FIG. 22** is a block diagram of a defibrillator **419**C incorporating an optical pulse detector with a temperature sensor **434**. Defibrillator **419**C corresponds substantially to defibrillator **419**B, but further includes temperature sensor **434**. Temperature sensor **434** may be realized by any suitable temperature sensing device, such as a thermistor, thermocouple, solid state temperature sensor, or the like, which may be placed on the patient's body, e.g., adjacent light detector module **432**. A temperature interface **432** may be provided to amplify and process a temperature signal generated by temperature sensor **434** for evaluation by processor **424** in conjunction with the light detection signal obtained from light detection interface **428**.

[**0220**] Processor **424** may correlate the light detection signal with a temperature range indicated by the temperature sensor **434** in order to compensate the light detection signal for temperature-induced variations, and more accurately derive physiological parameters for cardiac pulse detection. In addition, processor **424** uses the temperature signal generated by photodetector sensor **428** to assess the change in the absorption coefficient and/or the scattering coefficient of the tissue or blood into which the light is transmitted by light source **427** as a function of temperature. Processor **424** may correlate the light detection signal with a temperature range indicated by the temperature sensor **434** in order to compensate the light detection signal for temperature-induced variations, and more accurately derive physiological parameters for cardiac pulse detection.

[**0221**] **FIG. 23** is a diagram of a defibrillator electrode **420**A incorporating an optical pulse detector **422** attached to the defibrillation electrode. **FIG. 24** illustrates detachment of optical pulse detector **422** from defibrillation electrode **420**A. Optical pulse detector **422** may include a single or multiple light sources and light detectors as shown in the examples of FIGS. **20-24**, and may operate substantially as described above. In addition, optical pulse detector **422** may be detachably coupled to defibrillation electrode **420**, e.g., by adhesive tape, hook-and-loop fasteners, snap fits, friction fits, or tear-away joints. In this manner, optical pulse detector **422** may be initially attached to defibrillation electrode **420**A, but then detached by the user.

[**0222**] For example, the optical pulse detector **422** may be placed on the body of the patient at a first location with defibrillation electrode **420** to obtain a first pulse detection, and then detached and placed at a second location to obtain a second pulse detection. The first and second pulse detections may be evaluated together to obtain a more reliable indication of a cardiac pulse. Alternatively, the user may elect to detach optical pulse detector **422** and move it to a different position if the first position is not providing an acceptable detection signal. In each case, the first location may be on the chest or abdomen of the patient while the second position may be on the neck or forehead of the patient.

[**0223**] **FIG. 25** is a graph illustrating a light detection signal with a dc component. As shown in **FIG. 26**, the light detection **438** may have a generally pulsatile waveform, as well as a significant de component **440** that adds an offset to the waveform. As a further embodiment of the invention, any of the defibrillators **419** of FIGS. **20-22** may further incorporate a circuit or a processor-implemented routine to extract dc component **440** of the light detection signal **438**. In this case, the intensity level of a light source **421, 423, 427** may be adjusted according to the extracted dc component, or an amplifier gain within light detection module **422** or light detection interface **428** may be adjusted according to the extracted dc component. Additionally, in some embodiments, the intensity of the light source **421, 423, 427** may be varied as a function of temperature. In each case, the result may be a more accurate derivation of a physiological parameters based on the light detection signal, and hence a more reliable cardiac pulse detection.

[0224] **FIG. 26** is a flow diagram illustrating a technique for cardiac pulse detection based on a light detection signal. The technique illustrated in **FIG. 27** may be performed by one or more of the medical devices described in FIGS. **20-22**. As shown in **FIG. 26**, the technique includes transmitting light into a patient (**442**), receiving the transmitted light via a light detector (**444**), and generating a light detection signal (**446**) based on the transmitted light. The technique further includes processing the light detection signal to ascertain a physiological parameter (**448**), such as a trend in pulsatile changes in blood volume, and generate a cardiac pulse detection indication based on the physiological parameter (**450**). The user is provided with information concerning treatment of the patient, or treatment itself, based on the trend in pulsatile changes of blood volume. For example, other actions, such as issuance of instructions for delivery of CPR, or indication of other conditions, may be taken in response to the indication.

[0225] **FIG. 27** is a flow diagram illustrating an exemplary operation of a medical device, such as one of medical devices **419**A-C, to indicate conditions of a patient or therapy to be delivered to the patient based on the absence of pulsatile blood flow as detected via an optical pulse detector **422**, **432**. Specifically, **FIG. 27** illustrates a operation of a medical device **419** to monitor electrical activity of a heart of the patient, and indicate the occurrence of non-shockable pulseless electrical activity (PEA), or indicate delivery of a defibrillation shock where a ventricular tachycardia or fibrillation rhythm is not accompanied by pulsatile blood flow, e.g., where the ventricular tachycardia or fibrillation is shockable. The medical device **419** may include an ECG signal amplifier **52**, ECG bandpass filter **54**, and A/D converter **36** as described with reference to **FIG. 3**, and may detect electrical activity of the heart of the patient via electrodes **420**A and **420**B, or other electrodes dedicated ECG detection.

[0226] The medical device **419** transmits light into the patient (**462**), and receives the transmitted light (**464**) to generate a light detection signal according to any of the above-described techniques (**466**). The medical device **419** processes the light detection signal to determine whether pulsatile blood flow is present according to any of the above-described techniques (**468**). If the medical device **419** determines that pulsatile blood flow is not present, the medical device may indicate the absence of pulsatile blood flow to a user.

[0227] The medical device **419** analyzes the electrical activity within the heart of the patient, e.g., the ECG of the patient. If the medical device **419** does not detect electrical activity indicative of ventricular depolarizations (**470**), e.g., the ECG does not contain appreciable R-waves and/or the patient is in asystole, the medical device **419** may prompt the user to deliver a defibrillation shock or automatically deliver a defibrillation shock (**478**). If the medical device **119** detects electrical activity that is indicative ventricular tachycardia (VT) or ventricular fibrillation (VF) and that pulsatile blood flow is not present (**472**), e.g., detects a shockable VT or VF, the medical device **119** may prompt the user to deliver a defibrillation shock or automatically deliver a defibrillation shock (**478**). If the medical device **419** detects electrical activity that is not VT or VF, but determines that pulsatile blood flow is not present, the medical device may indicate the occurrence of PEA to the user so that appropriate therapy may be provided to the patient (**474**). The medical device **419** may indicate the need for the user to provide CPR, and/or may provide instructions for the provision of CPR to the user (**476**). In some embodiments, the medical device **419** may trigger automatic delivery of CPR via a CPR delivery device, which may be a component of the medical device.

[0228] **FIG. 28** is a flow diagram illustrating an exemplary operation of a medical device **419** to report the return of spontaneous circulation (ROSC) in a patient after delivery of a defibrillation shock to the patient. The medical device **419** delivers a defibrillation shock to the patient via electrodes **420**A and **420**B (**482**). The medical device **419** transmits light into the patient (**484**), and receives the transmitted light (**486**) to generate a light detection signal according to any of the above-described techniques (**488**). The medical device **419** processes the light detection signal to determine whether pulsatile blood flow is present according to any of the above-described techniques (**490**). If the medical device **419** determines that pulsatile blood flow is present, the medical device indicates ROSC to a user (**492**). If the medical device **419** determines that pulsatile blood flow is not present, the medical device may prompt a user for delivery of, or automatically deliver another defibrillation shock via electrodes **420**A and **420**B.

[0229] **FIG. 29** is a flow diagram illustrating an exemplary operation of a medical device, such as one of medical devices **419**A-C, to deliver pacing therapy to a patient. Specifically, **FIG. 29** illustrates operation of a medical device **419** to automatically detect capture of the heart of the patient by delivered pacing pulses based on pulsatile blood flow, and adjust the amplitude or timing of pacing pulses to maintain capture. The medical device **419** may include pacing pulse generation and timing circuitry known in the medical device arts, and may deliver pacing pulses via electrodes **420**A and **420**B, or other electrodes dedicated to delivery of pacing pulses.

[0230] The medical device **419** delivers a pacing pulse to the patient (**502**). The medical device **419** transmits light into the patient (**504**), and receives the transmitted light (**506**) to generate a light detection signal according to any of the above-described techniques (**508**). The medical device **419** processes the light detection signal to determine whether pulsatile blood flow is present according to any of the above-described techniques (**510**).

[0231] Absence of pulsatile blood flow in response to delivery of a pacing pulse indicates that the pacing pulse did not capture the heart of the patient. Consequently, the medical device may increase a voltage or current pacing pulse amplitude, or decrease a timing interval used to control delivery of the pacing pulse, in response to detection of an absence of pulsatile blood flow subsequent to delivery of a pacing pulse (**512**). This technique may allow the medical device **419** to maintain capture during delivery of a pacing therapy.

[0232] The invention additionally provides methods and algorithms as described above. The methods and algorithms presented above are not necessarily inherently associated with any particular computing device or other apparatus. Rather, various general purpose machines may be used with programs in accordance with the teachings herein, or it may prove more convenient to construct more specialized appa-

ratus to perform the required method steps. The required structure for a variety of these machines is apparent from the description herein.

[0233] In all cases, it should be borne in mind the distinction between the method of the invention itself and the method of operating a computing machine. The present invention relates to both methods in general, and also to steps for operating a computer and for processing electrical or other physical signals to generate other desired physical signals.

[0234] The invention additionally provides programs and methods of program operation. A program is generally defined as a group of steps leading to a desired result. A program made according to an embodiment of the invention is most advantageously implemented as a program for a computing machine, such as a defibrillator **10** or other equipment housing a general purpose computer, a special purpose computer, a microprocessor, etc.

[0235] The invention also provides storage media that, individually or in combination with others, have stored thereon instructions of a program made according to the invention. A storage medium according to the invention is a computer-readable medium, such as a memory **40** as noted above, and is read by the computing machine mentioned above.

[0236] It is readily apparent that the steps or instructions of a program made according to an embodiment of the invention requires physical manipulations of physical quantities. Usually, though not necessarily, these quantities may be transferred, combined, compared, and otherwise manipulated or processed according to the instructions, and they may also be stored in a computer-readable medium. These quantities include, for example, electrical, magnetic, and electromagnetic signals, and also states of matter that can be queried by such signals. It is convenient at times, principally for reasons of common usage, to refer to these quantities as signal data, bits, data bits, samples, values, symbols, characters, images, terms, numbers, or the like. It should be borne in mind, however, that all these and similar terms are associated with the appropriate physical quantities, that these terms are merely convenient labels applied to these physical quantities.

[0237] This detailed description is presented largely in terms of flowcharts, display images, algorithms, processes, and symbolic representations of operations of data bits within at least one computer readable medium. The present description achieves an economy in that a single set of flowcharts is used to describe both methods of the invention and programs according to the invention. Such descriptions and representations are the type of convenient labels used by those skilled in programming and/or data processing arts to effectively convey the substance of their work to others skilled in the art. A person skilled in the art of programming may use these descriptions to readily generate specific instructions for implementing a program according to the present invention.

[0238] Often, and for the sake of convenience only, it is preferred to implement and describe a program as various interconnected distinct software modules or features, individually and collectively also known as software, though such modules may equivalently be aggregated into a single program with unclear boundaries. The software modules or features of the present invention may be implemented by themselves, or in combination with others. Although the program may be stored in a computer-readable medium, such as a memory **40**, a person skilled in the art will readily recognize that it need not be a single memory, or even a single machine. Various portions, modules, or features of the program may reside in separate memories, or even separate machines. The separate machines may be connected directly, or through a network, such as a local area network (LAN), or a global network, such as the Internet, by wired or wireless connections. For example, a data acquisition unit may collect the accelerometer signal data obtained in the present invention and communicate the data to a remote computing machine for analysis and report whether a cardiac pulse is present.

[0239] It will be appreciated that some of the methods described herein may include software steps that can be performed by different modules of an overall software architecture. For example, data forwarding in a router may be performed in a data plane, which consults a local routing table. Collection of performance data may also be performed in a data plane. The performance data may be processed in a control plane, which accordingly may update the local routing table, in addition to neighboring ones. A person skilled in the art will discern which step is performed in which plane.

[0240] In any event, in the present case, methods of the invention are implemented by machine operations. In other words, embodiments of programs of the invention are made such that they perform methods of the invention as described above. These may optionally be performed in conjunction with one or more human operators performing some, but not all of them. As per the above, these need not be co-located with each other, but each only with a machine that houses a portion of the program. Alternatively, some of these machines may operate automatically, without users and/or independently from each other.

[0241] While various exemplary embodiments of the invention have been illustrated and described herein, persons having ordinary skill in the art will recognize variations of the same that are fully with the scope of the invention. Embodiments of the invention described herein are shown processing digital physiological signal data. However, the invention also includes embodiments in which the physiological signal data is not converted to digital form, but remains in analog form. References to "data" thus encompass both digital and analog signal formats. Moreover, references to "physiological signal data" may refer to a raw physiological signal itself or signal information derived from the physiological signal in either digital or analog form. Various embodiments of the invention have been described. These and other embodiments are within the scope of the following claims.

1. A method comprising:

transmitting light into a patient;

receiving light that has been transmitted into the patient;

generating a light detection signal in response to the received light;

processing the light detection signal over a period of time to detect a trend in pulsatile changes in blood volume; and

providing at least one of treatment and information concerning treatment based on the trend in pulsatile changes blood volume.

2. The method of claim 1, further comprising:

detecting a temperature; and

compensating the light detection signal based on the detected temperature.

3. The method of claim 1, wherein transmitting light include transmitting a first light into the patient at a first wavelength, and transmitting a second light into the patient at a second wavelength, and receiving light includes receiving the first light and the second light.

4. The method of claim 3, wherein the first light is red light and the second light is near-infrared light.

5. A method comprising:

transmitting first light into a patient at a first wavelength;

transmitting second light into a patient at a second wavelength;

receiving the first and second light that has been transmitted into the patient;

generating a light detection signal in response to the received light; and

processing the light detection signal to detect a physiological parameter indicative of a cardiac pulse.

6. The method of claim 5, wherein the first light is red light and the second light is near-infrared light.

7. The method of claim 5, wherein transmitting light includes transmitting the first light from a first light source, and transmitting the second light from a second light source.

8. The method of claim 5, further comprising indicating at least one of prompting for CPR, a spontaneous return to circulation, Pulseless Electrical Activity, a modification in pacing stimuli, and delivery of defibrillation therapy in response to the presence of a pulse.

9. The method of claim 5, further comprising identifying an artifact in the light detection signal, wherein the artifact is caused by at least one of an environmental artifact and an optical artifact.

10. A medical device comprising:

a light source to transmit light into a patient;

a sensor to receive light that has been transmitted into the patient;

a circuit to generate a light detection signal in response to the received light; and

a processor to process the light detection signal to detect presence of a cardiac pulse, and provide at least one of treatment and information concerning treatment based on the presence of the cardiac pulse.

11. The medical device of claim 10, further comprising a temperature sensor to generate a temperature signal from a temperature sensor, wherein the processor compensates the light detection signal based on the temperature signal.

12. The medical device of claim 10, wherein the light source transmits a first light into the patient at a first wavelength, and transmits a second light into the patient at a second wavelength, and the sensor receives both the first light and the second light.

13. The medical device of claim 12, wherein the first light is red light and the second light is near-infrared light.

14. A medical device comprising:

a light source to transmit a first light into a patient at a first wavelength and a second light into the patient at a second wavelength;

a sensor to receive the first and second light that has been transmitted into the patient;

a circuit to generate a light detection signal in response to the received light;

a processor to process the light detection signal to detect a physiological parameter indicative of presence of a cardiac pulse, and provide at least one of treatment and information concerning treatment based on physiological parameter.

15. The device of claim 14, further comprising a temperature sensor to generate a temperature signal from a temperature sensor, wherein the processor compensates the light detection signal based on the temperature signal.

16. The device of claim 14, wherein the light source includes a first light source to transmit the first light into the patient, and a second light source to transmit the second light into the patient.

17. The device of claim 16, wherein the first light is red light and the second light is near-infrared light.

18. The device of claim 14, wherein the processor indicates at least one of a spontaneous return to circulation, prompting for CPR, Pulseless Electrical Activity, a modification in pacing stimuli, and delivery of defibrillation therapy in response to the trend in pulsatile changes blood volume.

19. A method comprising:

applying a defibrillation electrode with a pulse detector to a first position of a patient;

performing a first pulse detection;

detaching the pulse detector from the defibrillation electrode; and

placing the detached pulse detector at a second position of the patient.

20. The method of claim 19, further comprising performing a second pulse detection with the pulse detector placed at the second position.

21. The method of claim 20, further comprising reattaching the pulse detector to the defibrillation electrode.

22. The method of claim 20, wherein the pulse detector is an optical pulse detector.

23. The method of claim 20, wherein the pulse detector is a mechanical detector.

24. A medical device comprising:

a defibrillation electrode; and

a pulse detector detachably coupled to the defibrillation electrode.

25. The device of claim 24, further comprising a processor to detect a pulse based on a first pulse detection performed

at a first position of a patient, and a second pulse detection performed upon detachment of the pulse sensor at a second position of a patient.

26. The device of claim 24, wherein the pulse sensor is reattachable to the defibrillation electrode upon detachment.

27. The device of claim 24, wherein the pulse sensor is an optical pulse sensor.

28. The device of claim 24, wherein the pulse detector is a mechanical detector.

29. A medical device comprising:

a defibrillation electrode; and

a light source for a pulse detector embedded in the defibrillation electrode.

30. A method comprising:

transmitting light into a patient at a first intensity;

receiving light transmitted into the patient at the first intensity to generate a first light detection signal;

transmitting light into the patient at a second intensity;

receiving light transmitted into the patient at the second intensity to generate a second light detection signal; and

processing the light detection signals to detect a physiological parameter indicative of presence of a cardiac pulse.

31. The method of claim 30, further comprising providing at least one of treatment and information concerning treatment based on the physiological parameter.

32. The method of claim 30, further comprising:

extracting a dc component of the first light detection signal; and

setting the second intensity according to the extracted dc component.

33. The method of claim 30, further comprising:

extracting a dc component of the first light detection signal; and

adjusting a gain of a light detector used to receive the light according to the extracted dc component.

34. A medical device comprising:

a light source that transmits light into a patient at a first intensity and a second intensity;

a light detector that receives light transmitted into the patient at the first intensity to generate a first light detection signal, and receives light transmitted into the patient at the second intensity to generate a second light detection signal; and

a processor that processes the light detection signals to detect a physiological parameter indicative of presence of a cardiac pulse.

35. The medical device of claim 34, wherein the processor provides at least one of treatment and information concerning treatment based on the physiological parameter.

36. The medical device of claim 34, wherein the processor extracts a dc component of the first light detection signal, and controls the light source to set the second intensity according to the extracted dc component.

37. The medical device of claim 34, wherein the processor extracts a dc component of the first light detection signal, and adjusts a gain of the light detector according to the extracted dc component.

38. A method comprising:

transmitting light into a patient;

receiving light that has been transmitted into the patient;

generating a light detection signal in response to the received light;

processing the light detection signal to detect pulsatile changes in blood volume; and

providing at least one of treatment and information concerning treatment based on the trend in pulsatile changes blood volume.

39. The method of claim 38, further comprising indicating at least one of prompting for CPR, a spontaneous return to circulation, Pulseless Electrical Activity, a modification in pacing stimuli, and delivery of defibrillation therapy in response to the presence of a pulse.

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